



STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

EXECUTIVE DIVISION
SPECIAL COUNSEL

September 9, 2015

Bishop Dr. Truman Berst
Alternative Remedies Health & Herbs
425 Ellsworth Street SW
Albany, Oregon 45202-1100

Re: Misbranding/Adulteration of Devil's Claw Dietary Supplements

Dear Bishop Dr. Berst,

This letter constitutes a demand that Alternative Remedies Health & Herbs cease and desist from the marketing, distribution, or sale of misbranded or adulterated devil's claw dietary supplements. For the reasons set forth below, we advise you to furnish the requested documentation and take immediate steps to identify and compensate any consumers who purchased misbranded or adulterated products.

The dietary supplements industry markets devil's claw—the commercial name for the plant *Harpagophytum procumbens* (“Devil's Claw”)—as a purported remedy for arthritis and chronic pain. An independent scientific analysis conducted at the New York Botanical Garden (“NYBG”) concluded that your company sold a devil's claw supplement derived, in whole or in part, from a different, cheaper species that is considered less desirable: *Harpagophytum zeyheri* (the “Substitute Plant”). This would violate several provisions of federal and New York law. *See, e.g.*, 21 U.S.C. §§ 331(a), 342-343; N.Y. Agric. & Mkts. Law § 199-a; N.Y. Gen. Bus. Law § 349.

Scientists affiliated with NYBG, a leading botanical research center, used a DNA barcoding technique to identify the relevant plant source for a range of supplements labeled as containing devil's claw or devil's claw extract.¹ The NYBG study revealed widespread substitution and adulteration; of 16 U.S. made devil's claw supplements where the relevant plant

¹ DNA barcoding is a sophisticated genetic technique that relies on short, unique sequences of DNA to identify the source of plant or animal material. To carry out the NYBG study, researchers first identified unique mini-barcodes, specifically focused on the *psbAtrnH* genetic marker, to distinguish between the two *Harpagophytum* species. The study analyzed 23 supplements labeled as containing devil's claw or a devil's claw extract, including both single-ingredient supplements and complex mixtures. Five of the tested supplements were produced by non-U.S. companies and labeled for overseas sale, and are therefore excluded from the results discussed in this letter. Of the 18 supplements labeled for sale in the United States, NYBG extracted identifiable DNA from all but two of the products. (Only one of the two is labeled as an “extract” in the “supplement facts” panel.)

source could be identified—produced by 14 separate companies, including large and small firms—**100%** were found to contain the Substitute Plant, either alone (81%) or in combination with Devil’s Claw (19%). According to subpoenaed documents, this included a product sold by your company as “Devil’s Claw Root,” Lot No. C0239 (the “Tested Lot”). Your product’s label did not disclose the presence of the Substitute Plant. The NYBG study concluded, however, that your company’s product contained the Substitute Plant, not Devil’s Claw.

Because of the implications for consumers, we are contacting your company prior to publication of the NYBG study. This analysis, however, is far from the first to draw attention to serious quality control and compliance problems in the supplement industry. Nor is it the first red flag indicating fraud, misidentification, or other serious problems in the supply chain for Devil’s Claw, a popular and scarce plant indigenous to the Kalahari Desert; reports of raw material suppliers mixing or replacing dried Devil’s Claw root tubers with the similar-looking dried root tubers of the Substitute Plant—a cheaper plant in the same genus—are common. In this context, the results of the NYBG study are especially troubling; they suggest an industry-wide failure to take necessary steps to comply with law and ensure the accuracy of claims concerning the quality and authenticity of the supplements marketed to consumers.

As a matter of commerce, science, and law, Devil’s Claw (*Harpagophytum procumbens*) and the Substitute Plant (*Harpagophytum zeyheri*) are distinct species:

- **Commercially**, Devil’s Claw is preferred in virtually all respects, is scarcer, and commands a higher market price. After contacting several suppliers, the Office of the New York Attorney General received price quotes for Devil’s Claw root that were *two- to three-times higher* than a similar quote for the Substitute Plant.
- **Scientifically**, the two plants are separate species that can be easily distinguished in the wild. Herbalists link the purported therapeutic properties of Devil’s Claw—which are not generally accepted in the medical community or approved by the FDA—to certain naturally-occurring chemical compounds, specifically iridoid glycosides. These chemicals tend to occur naturally in Devil’s Claw at much higher concentrations. They also appear in different ratios in the two plants, and at least one chemically potent phenol glycoside in Devil’s Claw (6-acetylacteoside) is missing from the Substitute Plant. Moreover, supplements derived from the Substitute Plant—even those “standardized” to deliver a promised percentage of certain iridoid glycosides—are also likely to expose users to other chemicals that are either absent from Devil’s Claw or present at lower concentrations.²

² Certain overseas jurisdictions allow the Substitute Plant to be sold as part of the same product as Devil’s Claw. This approach has been criticized in the scientific literature due, in part, to the distinct chemical profiles of the two plants and the lack of evidence that the two are pharmacologically equivalent. See, e.g., Nontobeko P. Mncwangi, et al., *What the devil is in your phytomedicine? Exploring species substitution in Harpagophytum through chemometric modeling of ¹H-NMR and UHPLC-MS datasets*, 106 *Phytochemistry* 104-115 (October 2014) (“[O]ur results clearly demonstrate a phytochemical disparity between the two species which may impact on their biological properties. . . . The chemometric analysis results showed that the two species are not chemically equivalent, particularly, that harpagoside is not always present in *H. zeyheri*, suggesting that the therapeutic outcome may be different, thus they should not be used interchangeably until pharmacological equivalence has been confirmed.”)

- Legally, the 1992 Edition of Herbs of Commerce supplies the list of plants that may be sold in the United States commercially under particular common names. 21 C.F.R. 101.4(h).³ The relevant definition—which was reaffirmed in the more recent edition—defines devil’s claw as *Harpagophytum procumbens*, *i.e.* as Devil’s Claw. Representing any plant other than Devil’s Claw as “devil’s claw” is inconsistent with the definition codified in the Herbs of Commerce and is misleading as a matter of law. Misapplying the common name is all the more problematic where, as here, the scientific name of the non-standard species appears nowhere on the label.

Nor are we convinced that the Substitute Plant would be lawful for sale in New York or elsewhere in the United States under its proper scientific name, *i.e.* as *Harpagophytum zeyheri*. Under federal law, a manufacturer may legally sell a “new dietary ingredient”—or an ingredient that was first marketed in the United States after October 15, 1994—if it was (i) used as a source of food; or (ii) submitted to the federal Food and Drug Administration as part of a new dietary ingredient notification at least 75 days prior to initial sale. *See* 21 U.S.C. § 350b; 21 U.S.C. § 331(a); *see also* FDA Draft Guidance on New Dietary Ingredient Notifications, Docket No. FDA-2011-D-0376 76, Fed. Reg. 39111 (July 5, 2011). First, Devil’s Claw has long been marketed in the United States, including as “grapple” and “harpagophytum root.” We have seen no comparable evidence establishing that the Substitute Plant, *i.e.* *Harpagophytum zeyheri*, was sold in the United States prior to 1994, except as an unwanted adulterant.⁴ Second, the Substitute Plant appears to satisfy neither of the requirements for new dietary ingredients.⁵

In connection with an investigation arising under N.Y. Exec. Law § 63(12), N.Y. Gen. Bus. Law § 349, N.Y. Agric. & Mkts. Law § 8, and other authorities, we therefore request a detailed, written response to this letter within 10 business days. In addition to offering you an opportunity to respond to, or dispute any of the analysis above, we ask that your response cover the topics and incorporate the materials identified in the attached Appendix, including but not limited to:

- (i) The methodology and results of any testing your company performs or has performed by a third party on the Tested Lot to independently verify the results of the NYBG study;
- (ii) Your company’s plans for identifying and, where appropriate, recalling any and all non-complying devil’s claw supplements;

³ Herbs of Commerce seeks to avoid confusion in the herbal supplements marketplace by applying “a single common name in trade . . . to only one botanical name.” *Id.* at I (introduction). The common name “devil’s claw” perfectly illustrates the problem. Overseas and in non-commercial settings, that name has been used loosely to refer to numerous species, including the Substitute Plant as well as other wholly unrelated plants like *Pisonia aculeate*, *Proboscidea altheaefolia*, and *Senegalia greggii*.

⁴ To the contrary, various sources dating back many years identify the Substitute Plant as an unwanted adulterant, which was not legally exported internationally until European standards were loosened in 2003.

⁵ Like many traditional herbal supplements, Devil’s Claw may be administered orally, including as a tea. This does not convert it or the Substitute Plant into a source of food for purposes of the new dietary ingredient requirements.

- (iii) Your company's proposal for identifying and, where appropriate, compensating any defrauded or otherwise harmed consumers; and
- (iv) Any and all new reforms your company will implement to ensure the quality and authenticity of the herbal supplements it manufactures or distributes, including new analytical testing methods.

Notwithstanding this response, we further advise you to preserve and retain any and all documents and communications concerning the subjects addressed in this letter, including but not limited to: (i) the sourcing of ingredients for devil's claw and other herbal dietary supplements; (ii) the measures used to verify the reliability of suppliers of devil's claw and other herbal ingredients; (iii) quality control for devil's claw and other herbal dietary supplements, including awareness of misidentification of herbal products and financially motivated adulteration, with respect to raw materials or finished products; (iv) the labeling and marketing of devil's claw and other herbal supplements; and (v) the manufacturing protocols and testing methods employed to ensure the accuracy of all label and marketing claims relating to the identity, purity, potency, or other characteristics of devil's claw and other herbal supplements.

Please do not hesitate to reach out to our office with any questions or concerns.

Respectfully,



Simon G. Brandler
Senior Advisor & Special Counsel
212-416-6544 / Simon.Brandler@ag.ny.gov

APPENDIX

Request for Additional Documentation and Information

With your response, please furnish the following information or documentation:

- (1) For each shipment of ingredients or products your company received since January 1, 2012 that were purportedly derived, in whole or in part, from Devil's Claw and/or the Substitute Plant (the "DC Ingredients"):
 - a. The name, address, telephone number, email address, and other contact information for the supplier from whom your company obtained the shipment;
 - b. The supplier's descriptions of the content of the shipment, as they appeared on order forms, packing slips, contracts, and other written materials;
 - c. The date your company received the shipment;
 - d. The address where your company received the shipment;
 - e. The form in which the DC Ingredients arrived (e.g. powdered extract, cut-and-dried tubers, powdered whole herbs, etc.);
 - f. The address or addresses of the manufacturing facilities that produced any finished supplements containing the DC Ingredients;
 - g. The volume in kilograms of DC Ingredients received;
 - h. The total price your company paid for the DC Ingredients in the shipment in U.S. dollars; and
 - i. Copies of all product labels (front and back) for all supplements produced using the DC Ingredients in that shipment.
- (2) Copies of all audits, reviews, or other documents or communications prepared by your company or a third party to assess the reliability of any supplier who sold DC Ingredients to your company from January 1, 2012 to the present, and a description of any other verification measures not reflected in such documents and communications;
- (3) Copies of all documents and communications, including but not limited to order forms, contracts, packing slips, contracts, correspondence, or other written or electronic materials, concerning the shipment or shipments of DC Ingredients used in manufacturing the Tested Lot;
- (4) A complete description of the methodology and copies of the results of any testing or analyses your company performed or had performed from January 1, 2012 to the present on DC Ingredients or on finished dietary supplements containing DC Ingredients for identity, potency, purity, or any other characteristic, along with a

statement indicating whether any such testing could distinguish between Devil's Claw and the Substitute Plant;

- (5) A complete description of the testing or other measures your company undertook, is undertaking, or intends to undertake to determine the degree to which the products it sold since January 1, 2012 purporting to contain DC Ingredients were adulterated or misbranded, including but not limited to the Tested Lot;
- (6) The results of any and all testing described in response to Item 5 or of any other testing performed on the Tested Lot;
- (7) Copies of any and all documents or communications concerning the Tested Lot or its sale;
- (8) Copies of all documents and communications your company sent to, received from, or exchanged with any employee or agent of the federal Food and Drug Administration ("FDA") since January 1, 2012 concerning inspections of the company facilities identified in response to Item 1(f) above, including but not limited to Form 483s and your company's response thereto.
- (9) For each year from January 1, 2012 to the present, the total annual revenue or, for 2015, the year-to-date revenue your company received respectively from the sale of dietary supplements containing DC Ingredients in (i) retail sales in New York State; (ii) Internet sales to New York State residents; and (iii) the United States overall;
- (10) A proposal for identifying and, as appropriate, compensating any purchasers of devil's claw supplements your company manufactured who may have received adulterated or misbranded products; and
- (11) A complete description of improvements, safeguards, or reforms your company will implement to avoid adulteration or misbranding of herbal dietary supplements in the future, including but not limited to testing or other measures to detect and prevent the adulteration or misbranding of supplement's containing DC Ingredients.



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EXECUTIVE DIVISION
SPECIAL COUNSEL

September 9, 2015

Biopower Nutrition
c/o Magdalena Rozio
Azorio, LLC
333 Kendall Drive
Marco Island, Florida 34145-2432

Re: Misbranding/Adulteration of Devil's Claw Dietary Supplements

To Whom It May Concern,

This letter constitutes a demand that Biopower Nutrition¹ cease and desist from the marketing, distribution, or sale of misbranded or adulterated devil's claw dietary supplements. For the reasons set forth below, we advise Biopower Nutrition to furnish the requested documentation and take immediate steps to identify and compensate any consumers who purchased misbranded or adulterated products.

The dietary supplements industry markets devil's claw—the commercial name for the plant *Harpagophytum procumbens* (“Devil's Claw”)—as a purported remedy for arthritis and chronic pain. An independent scientific analysis conducted at the New York Botanical Garden (“NYBG”) concluded that Biopower Nutrition sold a devil's claw supplement derived, in whole or in part, from a different, cheaper species that is considered less desirable: *Harpagophytum zeyheri* (the “Substitute Plant”). This would violate several provisions of federal and New York law. *See, e.g.*, 21 U.S.C. §§ 331(a), 342-343; N.Y. Agric. & Mkts. Law § 199-a; N.Y. Gen. Bus. Law § 349.

Scientists affiliated with NYBG, a leading botanical research center, used a DNA barcoding technique to identify the relevant plant source for a range of supplements labeled as containing devil's claw or devil's claw extract.² The NYBG study revealed widespread

¹ We understand that Azorio, LLC sold or distributed products under the “Biopower Nutrition” label. If you are not the appropriate recipient, please forward this letter as appropriate or contact our office.

² DNA barcoding is a sophisticated genetic technique that relies on short, unique sequences of DNA to identify the source of plant or animal material. To carry out the NYBG study, researchers first identified unique mini-barcodes, specifically focused on the *psbAtrnH* genetic marker, to distinguish between the two *Harpagophytum* species. The study analyzed 23 supplements labeled as containing devil's claw or a devil's claw extract, including both single-ingredient supplements and complex mixtures. Five of the tested supplements were produced by non-U.S. companies and labeled for overseas sale, and are therefore excluded from the results discussed in this letter. Of the

substitution and adulteration; of 16 U.S. made devil's claw supplements where the relevant plant source could be identified—produced by 14 separate companies, including large and small firms—**100%** were found to contain the Substitute Plant, either alone (81%) or in combination with Devil's Claw (19%). According to subpoenaed documents, this included a product sold by Biopower Nutrition as “Devils Claw,” Lot No. 7032013 (the “Tested Lot”). The product's label failed to disclose the presence of the Substitute Plant. The NYBG study nonetheless concluded that the Devil's Claw product also contained the Substitute Plant.

Because of the implications for consumers, we are sending this letter prior to publication of the NYBG study. This analysis, however, is far from the first to draw attention to serious quality control and compliance problems in the supplement industry. Nor is it the first red flag indicating fraud, misidentification, or other serious problems in the supply chain for Devil's Claw, a popular and scarce plant indigenous to the Kalahari Desert; reports of raw material suppliers mixing or replacing dried Devil's Claw root tubers with the similar-looking dried root tubers of the Substitute Plant—a cheaper plant in the same genus—are common. In this context, the results of the NYBG study are especially troubling; they suggest an industry-wide failure to take necessary steps to comply with law and ensure the accuracy of claims concerning the quality and authenticity of the supplements marketed to consumers.

As a matter of commerce, science, and law, Devil's Claw (*Harpagophytum procumbens*) and the Substitute Plant (*Harpagophytum zeyheri*) are distinct species:

- **Commercially**, Devil's Claw is preferred in virtually all respects, is scarcer, and commands a higher market price. After contacting several suppliers, the Office of the New York Attorney General received price quotes for Devil's Claw root that were *two- to three-times higher* than a similar quote for the Substitute Plant.
- **Scientifically**, the two plants are separate species that can be easily distinguished in the wild. Herbalists link the purported therapeutic properties of Devil's Claw—which are not generally accepted in the medical community or approved by the FDA—to certain naturally-occurring chemical compounds, specifically iridoid glycosides. These chemicals tend to occur naturally in Devil's Claw at much higher concentrations. They also appear in different ratios in the two plants, and at least one chemically potent phenol glycoside in Devil's Claw (6-acetylacteoside) is missing from the Substitute Plant. Moreover, supplements derived from the Substitute Plant—even those “standardized” to deliver a promised percentage of certain iridoid glycosides—are also likely to expose users to other chemicals that are either absent from Devil's Claw or present at lower concentrations.³

18 supplements labeled for sale in the United States, NYBG extracted identifiable DNA from all but two of the products. (Only one of the two is labeled as an “extract” in the “supplement facts” panel.)

³ Certain overseas jurisdictions allow the Substitute Plant to be sold as part of the same product as Devil's Claw. This approach has been criticized in the scientific literature due, in part, to the distinct chemical profiles of the two plants and the lack of evidence that the two are pharmacologically equivalent. See, e.g., Nontobeko P. Mncwangi, et al., *What the devil is in your phytochemistry? Exploring species substitution in Harpagophytum through chemometric modeling of ¹H-NMR and UHPLC-MS datasets*, 106 *Phytochemistry* 104-115 (October 2014) (“[O]ur results clearly demonstrate a phytochemical disparity between the two species which may impact on their biological properties. . . . The chemometric analysis results showed that the two species are not chemically equivalent, particularly, that

- Legally, the 1992 Edition of Herbs of Commerce supplies the list of plants that may be sold in the United States commercially under particular common names. 21 C.F.R. 101.4(h).⁴ The relevant definition—which was reaffirmed in the more recent edition—defines devil’s claw as *Harpagophytum procumbens*, *i.e.* as Devil’s Claw. Representing any plant other than Devil’s Claw as “devil’s claw” is inconsistent with the definition codified in the Herbs of Commerce and is misleading as a matter of law. Misapplying the common name is all the more problematic where, as here, the scientific name of the non-standard species appears nowhere on the label.

Nor are we convinced that the Substitute Plant would be lawful for sale in New York or elsewhere in the United States under its proper scientific name, *i.e.* as *Harpagophytum zeyheri*. Under federal law, a manufacturer may legally sell a “new dietary ingredient”—or an ingredient that was first marketed in the United States after October 15, 1994—if it was (i) used as a source of food; or (ii) submitted to the federal Food and Drug Administration as part of a new dietary ingredient notification at least 75 days prior to initial sale. *See* 21 U.S.C. § 350b; 21 U.S.C. § 331(a); *see also* FDA Draft Guidance on New Dietary Ingredient Notifications, Docket No. FDA-2011-D-0376 76, Fed. Reg. 39111 (July 5, 2011). First, Devil’s Claw has long been marketed in the United States, including as “grapple” and “harpagophytum root.” We have seen no comparable evidence establishing that the Substitute Plant, *i.e.* *Harpagophytum zeyheri*, was sold in the United States prior to 1994, except as an unwanted adulterant.⁵ Second, the Substitute Plant appears to satisfy neither of the requirements for new dietary ingredients.⁶

In connection with an investigation arising under N.Y. Exec. Law § 63(12), N.Y. Gen. Bus. Law § 349, N.Y. Agric. & Mkts. Law § 8, and other authorities, we therefore request a detailed, written response to this letter from Biopower Nutrition within 10 business days. In addition to offering an opportunity to respond to, or dispute any of the analysis above, we ask that the response cover the topics and incorporate the materials identified in the attached Appendix, including but not limited to:

- (i) The methodology and results of any testing the company performs or has performed by a third party on the Tested Lot to independently verify the results of the NYBG study;
- (ii) The company’s plans for identifying and, where appropriate, recalling any and all non-complying devil’s claw supplements;

harpagoside is not always present in *H. zeyheri*, suggesting that the therapeutic outcome may be different, thus they should not be used interchangeably until pharmacological equivalence has been confirmed.”)

⁴ Herbs of Commerce seeks to avoid confusion in the herbal supplements marketplace by applying “a single common name in trade . . . to only one botanical name.” *Id.* at I (introduction). The common name “devil’s claw” perfectly illustrates the problem. Overseas and in non-commercial settings, that name has been used loosely to refer to numerous species, including the Substitute Plant as well as other wholly unrelated plants like *Pisonia aculeate*, *Proboscidea altheaefolia*, and *Senegalia greggii*.

⁵ To the contrary, various sources dating back many years identify the Substitute Plant as an unwanted adulterant, which was not legally exported internationally until European standards were loosened in 2003.

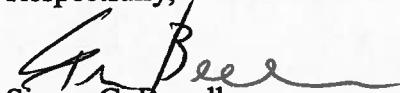
⁶ Like many traditional herbal supplements, Devil’s Claw may be administered orally, including as a tea. This does not convert it or the Substitute Plant into a source of food for purposes of the new dietary ingredient requirements.

- (iii) The company's proposal for identifying and, where appropriate, compensating any defrauded or otherwise harmed consumers; and
- (iv) Any and all new reforms Biopower Nutrition will implement to ensure the quality and authenticity of the herbal supplements it manufactures or distributes, including new analytical testing methods.

Notwithstanding this response, we further advise you to preserve and retain any and all documents and communications concerning the subjects addressed in this letter, including but not limited to: (i) the sourcing of ingredients for devil's claw and other herbal dietary supplements; (ii) the measures used to verify the reliability of suppliers of devil's claw and other herbal ingredients; (iii) quality control for devil's claw and other herbal dietary supplements, including awareness of misidentification of herbal products and financially motivated adulteration, with respect to raw materials or finished products; (iv) the labeling and marketing of devil's claw and other herbal supplements; and (v) the manufacturing protocols and testing methods employed to ensure the accuracy of all label and marketing claims relating to the identity, purity, potency, or other characteristics of devil's claw and other herbal supplements.

Please do not hesitate to reach out to our office with any questions or concerns.

Respectfully,



Simon G. Brandler
Senior Advisor & Special Counsel
212-416-6544 / Simon.Brandler@ag.ny.gov

APPENDIX

Request for Additional Documentation and Information

With the response, please furnish the following information or documentation:

- (1) For each shipment of ingredients or products Biopower Nutrition received since January 1, 2012 that were purportedly derived, in whole or in part, from Devil's Claw and/or the Substitute Plant (the "DC Ingredients"):
 - a. The name, address, telephone number, email address, and other contact information for the supplier from whom Biopower Nutrition obtained the shipment;
 - b. The supplier's descriptions of the content of the shipment, as they appeared on order forms, packing slips, contracts, and other written materials;
 - c. The date Biopower Nutrition received the shipment;
 - d. The address where Biopower Nutrition received the shipment;
 - e. The form in which the DC Ingredients arrived (e.g. powdered extract, cut-and-dried tubers, powdered whole herbs, etc.);
 - f. The address or addresses of the manufacturing facilities that produced any finished supplements containing the DC Ingredients;
 - g. The volume in kilograms of DC Ingredients received;
 - h. The total price Biopower Nutrition paid for the DC Ingredients in the shipment in U.S. dollars; and
 - i. Copies of all product labels (front and back) for all supplements produced using the DC Ingredients in that shipment.
- (2) Copies of all audits, reviews, or other documents or communications prepared by Biopower Nutrition or a third party to assess the reliability of any supplier who sold DC Ingredients to Biopower Nutrition from January 1, 2012 to the present, and a description of any other verification measures not reflected in such documents and communications;
- (3) Copies of all documents and communications, including but not limited to order forms, contracts, packing slips, contracts, correspondence, or other written or electronic materials, concerning the shipment or shipments of DC Ingredients used in manufacturing the Tested Lot;
- (4) A complete description of the methodology and copies of the results of any testing or analyses Biopower Nutrition performed or had performed from January 1, 2012 to the

present on DC Ingredients or on finished dietary supplements containing DC Ingredients for identity, potency, purity, or any other characteristic, along with a statement indicating whether any such testing could distinguish between Devil's Claw and the Substitute Plant;

- (5) A complete description of the testing or other measures Biopower Nutrition undertook, is undertaking, or intends to undertake to determine the degree to which the products it sold since January 1, 2012 purporting to contain DC Ingredients were adulterated or misbranded, including but not limited to the Tested Lot;
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- (7) Copies of any and all documents or communications concerning the Tested Lot or its sale;
- (8) Copies of all documents and communications Biopower Nutrition sent to, received from, or exchanged with any employee or agent of the federal Food and Drug Administration ("FDA") since January 1, 2012 concerning inspections of the company facilities identified in response to Item 1(f) above, including but not limited to Form 483s and Biopower Nutrition's response thereto.
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- (10) A proposal for identifying and, as appropriate, compensating any purchasers of devil's claw supplements Biopower Nutrition manufactured who may have received adulterated or misbranded products; and
- (11) A complete description of improvements, safeguards, or reforms Biopower Nutrition will implement to avoid adulteration or misbranding of herbal dietary supplements in the future, including but not limited to testing or other measures to detect and prevent the adulteration or misbranding of supplement's containing DC Ingredients.



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EXECUTIVE DIVISION
SPECIAL COUNSEL

September 9, 2015

Tim A. Gerke
Chief Executive Officer
Food Science Corporation
20 New England Drive, Suite 10
Essex Junction, Vermont 05452

Re: Misbranding/Adulteration of Devil's Claw Dietary Supplements

Dear Mr. Gerke,

This letter constitutes a demand that Food Science Corporation cease and desist from the marketing, distribution, or sale of misbranded or adulterated devil's claw dietary supplements. For the reasons set forth below, we advise you to furnish the requested documentation and take immediate steps to identify and compensate any consumers who purchased misbranded or adulterated products.

The dietary supplements industry markets devil's claw—the commercial name for the plant *Harpagophytum procumbens* (“Devil's Claw”)—as a purported remedy for arthritis and chronic pain. An independent scientific analysis conducted at the New York Botanical Garden (“NYBG”) concluded that your company sold devil's claw supplements derived, in whole or in part, from a different, cheaper species that is considered less desirable: *Harpagophytum zeyheri* (the “Substitute Plant”). This would violate several provisions of federal and New York law. *See, e.g.*, 21 U.S.C. §§ 331(a), 342-343; N.Y. Agric. & Mkts. Law § 199-a; N.Y. Gen. Bus. Law § 349.

Scientists affiliated with NYBG, a leading botanical research center, used a DNA barcoding technique to identify the relevant plant source for a range of supplements labeled as containing devil's claw or devil's claw extract.¹ The NYBG study revealed widespread

¹ DNA barcoding is a sophisticated genetic technique that relies on short, unique sequences of DNA to identify the source of plant or animal material. To carry out the NYBG study, researchers first identified unique mini-barcodes, specifically focused on the *psbAtrnH* genetic marker, to distinguish between the two *Harpagophytum* species. The study analyzed 23 supplements labeled as containing devil's claw or a devil's claw extract, including both single-ingredient supplements and complex mixtures. Five of the tested supplements were produced by non-U.S. companies and labeled for overseas sale, and are therefore excluded from the results discussed in this letter. Of the 18 supplements labeled for sale in the United States, NYBG extracted identifiable DNA from all but two of the products. (Only one of the two is labeled as an “extract” in the “supplement facts” panel.)

substitution and adulteration; of 16 U.S. made devil's claw supplements where the relevant plant source could be identified—produced by 14 separate companies, including large and small firms—**100%** were found to contain the Substitute Plant, either alone (81%) or in combination with Devil's Claw (19%). According to subpoenaed documents, these included two products sold by your company (the "Tested Lots"): "DaVinci Laboratories of Vermont Devil's Claw," Lot No. 21141800 1015, and "FoodScience of Vermont Devil's Claw," Lot No. 19046700 0815. The products' labels expressly identified the species as "*Harpagophytum procumbens*," i.e. as Devil's Claw. The NYBG study concluded that both products instead contained the Substitute Plant.

Because of the implications for consumers, we are contacting your company prior to publication of the NYBG study. This analysis, however, is far from the first to draw attention to serious quality control and compliance problems in the supplement industry. Nor is it the first red flag indicating fraud, misidentification, or other serious problems in the supply chain for Devil's Claw, a popular and scarce plant indigenous to the Kalahari Desert; reports of raw material suppliers mixing or replacing dried Devil's Claw root tubers with the similar-looking dried root tubers of the Substitute Plant—a cheaper plant in the same genus—are common. In this context, the results of the NYBG study are especially troubling; they suggest an industry-wide failure to take necessary steps to comply with law and ensure the accuracy of claims concerning the quality and authenticity of the supplements marketed to consumers.

As a matter of commerce, science, and law, Devil's Claw (*Harpagophytum procumbens*) and the Substitute Plant (*Harpagophytum zeyheri*) are distinct species:

- **Commercially**, Devil's Claw is preferred in virtually all respects, is scarcer, and commands a higher market price. After contacting several suppliers, the Office of the New York Attorney General received price quotes for Devil's Claw root that were *two- to three-times higher* than a similar quote for the Substitute Plant.
- **Scientifically**, the two plants are separate species that can be easily distinguished in the wild. Herbalists link the purported therapeutic properties of Devil's Claw—which are not generally accepted in the medical community or approved by the FDA—to certain naturally-occurring chemical compounds, specifically iridoid glycosides. These chemicals tend to occur naturally in Devil's Claw at much higher concentrations. They also appear in different ratios in the two plants, and at least one chemically potent phenol glycoside in Devil's Claw (6-acetylacteoside) is missing from the Substitute Plant. Moreover, supplements derived from the Substitute Plant—even those "standardized" to deliver a promised percentage of certain iridoid glycosides—are also likely to expose users to other chemicals that are either absent from Devil's Claw or present at lower concentrations.²

² Certain overseas jurisdictions allow the Substitute Plant to be sold as part of the same product as Devil's Claw. This approach has been criticized in the scientific literature due, in part, to the distinct chemical profiles of the two plants and the lack of evidence that the two are pharmacologically equivalent. See, e.g., Nontobeko P. Mncwangi, et al., *What the devil is in your phytomedicine? Exploring species substitution in Harpagophytum through chemometric modeling of ¹H-NMR and UHPLC-MS datasets*, 106 *Phytochemistry* 104-115 (October 2014) ("[O]ur results clearly demonstrate a phytochemical disparity between the two species which may impact on their biological properties. . . . The chemometric analysis results showed that the two species are not chemically equivalent, particularly, that

- Legally, the 1992 Edition of Herbs of Commerce supplies the list of plants that may be sold in the United States commercially under particular common names. 21 C.F.R. 101.4(h).³ The relevant definition—which was reaffirmed in the more recent edition—defines devil’s claw as *Harpagophytum procumbens*, i.e. as Devil’s Claw. Representing any plant other than Devil’s Claw as “devil’s claw” is inconsistent with the definition codified in the Herbs of Commerce and is misleading as a matter of law. Misapplying the common name is all the more problematic where, as here, the scientific name of the non-standard species appears nowhere on the label.

Nor are we convinced that the Substitute Plant would be lawful for sale in New York or elsewhere in the United States under its proper scientific name, i.e. as *Harpagophytum zeyheri*. Under federal law, a manufacturer may legally sell a “new dietary ingredient”—or an ingredient that was first marketed in the United States after October 15, 1994—if it was (i) used as a source of food; or (ii) submitted to the federal Food and Drug Administration as part of a new dietary ingredient notification at least 75 days prior to initial sale. See 21 U.S.C. § 350b; 21 U.S.C. § 331(a); see also FDA Draft Guidance on New Dietary Ingredient Notifications, Docket No. FDA-2011-D-0376 76, Fed. Reg. 39111 (July 5, 2011). First, Devil’s Claw has long been marketed in the United States, including as “grapple” and “harpagophytum root.” We have seen no comparable evidence establishing that the Substitute Plant, i.e. *Harpagophytum zeyheri*, was sold in the United States prior to 1994, except as an unwanted adulterant.⁴ Second, the Substitute Plant appears to satisfy neither of the requirements for new dietary ingredients.⁵

In connection with an investigation arising under N.Y. Exec. Law § 63(12), N.Y. Gen. Bus. Law § 349, N.Y. Agric. & Mkts. Law § 8, and other authorities, we therefore request a detailed, written response to this letter within 10 business days. In addition to offering you an opportunity to respond to, or dispute any of the analysis above, we ask that your response cover the topics and incorporate the materials identified in the attached Appendix, including but not limited to:

- (i) The methodology and results of any testing your company performs or has performed by a third party on the Tested Lots to independently verify the results of the NYBG study;
- (ii) Your company’s plans for identifying and, where appropriate, recalling any and all non-complying devil’s claw supplements;

harpagoside is not always present in *H. zeyheri*, suggesting that the therapeutic outcome may be different, thus they should not be used interchangeably until pharmacological equivalence has been confirmed.”)

³ Herbs of Commerce seeks to avoid confusion in the herbal supplements marketplace by applying “a single common name in trade . . . to only one botanical name.” *Id.* at I (introduction). The common name “devil’s claw” perfectly illustrates the problem. Overseas and in non-commercial settings, that name has been used loosely to refer to numerous species, including the Substitute Plant as well as other wholly unrelated plants like *Pisonia aculeate*, *Proboscidea altheaefolia*, and *Senegalia greggii*.

⁴ To the contrary, various sources dating back many years identify the Substitute Plant as an unwanted adulterant, which was not legally exported internationally until European standards were loosened in 2003.

⁵ Like many traditional herbal supplements, Devil’s Claw may be administered orally, including as a tea. This does not convert it or the Substitute Plant into a source of food for purposes of the new dietary ingredient requirements.

- (iii) Your company's proposal for identifying and, where appropriate, compensating any defrauded or otherwise harmed consumers; and
- (iv) Any and all new reforms your company will implement to ensure the quality and authenticity of the herbal supplements it manufactures or distributes, including new analytical testing methods.

Notwithstanding this response, we further advise you to preserve and retain any and all documents and communications concerning the subjects addressed in this letter, including but not limited to: (i) the sourcing of ingredients for devil's claw and other herbal dietary supplements; (ii) the measures used to verify the reliability of suppliers of devil's claw and other herbal ingredients; (iii) quality control for devil's claw and other herbal dietary supplements, including awareness of misidentification of herbal products and financially motivated adulteration, with respect to raw materials or finished products; (iv) the labeling and marketing of devil's claw and other herbal supplements; and (v) the manufacturing protocols and testing methods employed to ensure the accuracy of all label and marketing claims relating to the identity, purity, potency, or other characteristics of devil's claw and other herbal supplements.

Please do not hesitate to reach out to our office with any questions or concerns.

Respectfully,



Simon G. Brandler
Senior Advisor & Special Counsel
212-416-6544 / Simon.Brandler@ag.ny.gov

APPENDIX

Request for Additional Documentation and Information

With your response, please furnish the following information or documentation:

- (1) For each shipment of ingredients or products your company received since January 1, 2012 that were purportedly derived, in whole or in part, from Devil's Claw and/or the Substitute Plant (the "DC Ingredients"):
 - a. The name, address, telephone number, email address, and other contact information for the supplier from whom your company obtained the shipment;
 - b. The supplier's descriptions of the content of the shipment, as they appeared on order forms, packing slips, contracts, and other written materials;
 - c. The date your company received the shipment;
 - d. The address where your company received the shipment;
 - e. The form in which the DC Ingredients arrived (e.g. powdered extract, cut-and-dried tubers, powdered whole herbs, etc.);
 - f. The address or addresses of the manufacturing facilities that produced any finished supplements containing the DC Ingredients;
 - g. The volume in kilograms of DC Ingredients received;
 - h. The total price your company paid for the DC Ingredients in the shipment in U.S. dollars; and
 - i. Copies of all product labels (front and back) for all supplements produced using the DC Ingredients in that shipment.
- (2) Copies of all audits, reviews, or other documents or communications prepared by your company or a third party to assess the reliability of any supplier who sold DC Ingredients to your company from January 1, 2012 to the present, and a description of any other verification measures not reflected in such documents and communications;
- (3) Copies of all documents and communications, including but not limited to order forms, contracts, packing slips, contracts, correspondence, or other written or electronic materials, concerning the shipment or shipments of DC Ingredients used in manufacturing the Tested Lots;
- (4) A complete description of the methodology and copies of the results of any testing or analyses your company performed or had performed from January 1, 2012 to the present on DC Ingredients or on finished dietary supplements containing DC Ingredients for identity, potency, purity, or any other characteristic, along with a

statement indicating whether any such testing could distinguish between Devil's Claw and the Substitute Plant;

- (5) A complete description of the testing or other measures your company undertook, is undertaking, or intends to undertake to determine the degree to which the products it sold since January 1, 2012 purporting to contain DC Ingredients were adulterated or misbranded, including but not limited to the Tested Lots;
- (6) The results of any and all testing described in response to Item 5 or of any other testing performed on the Tested Lots;
- (7) Copies of any and all documents or communications concerning the Tested Lots or its sale;
- (8) Copies of all documents and communications your company sent to, received from, or exchanged with any employee or agent of the federal Food and Drug Administration ("FDA") since January 1, 2012 concerning inspections of the company facilities identified in response to Item 1(f) above, including but not limited to Form 483s and your company's response thereto.
- (9) For each year from January 1, 2012 to the present, the total annual revenue or, for 2015, the year-to-date revenue your company received respectively from the sale of dietary supplements containing DC Ingredients in (i) retail sales in New York State; (ii) Internet sales to New York State residents; and (iii) the United States overall;
- (10) A proposal for identifying and, as appropriate, compensating any purchasers of devil's claw supplements your company manufactured who may have received adulterated or misbranded products; and
- (11) A complete description of improvements, safeguards, or reforms your company will implement to avoid adulteration or misbranding of herbal dietary supplements in the future, including but not limited to testing or other measures to detect and prevent the adulteration or misbranding of supplement's containing DC Ingredients.



STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

EXECUTIVE DIVISION
SPECIAL COUNSEL

September 9, 2015

W. Rodney McMullen
Chief Executive Officer
The Kroger Co., as Parent of Vitacost.com
1014 Vine Street
Cincinnati, OH 45202-1100

Re: Misbranding/Adulteration of Devil's Claw Dietary Supplements

Dear Mr. McMullen,

This letter constitutes a demand that Vitacost.com, a wholly-owned subsidiary of The Kroger Co., cease and desist from the marketing, distribution, or sale of misbranded or adulterated devil's claw dietary supplements. For the reasons set forth below, we advise you to furnish the requested documentation and take immediate steps to identify and compensate any consumers who purchased misbranded or adulterated products.

The dietary supplements industry markets devil's claw—the commercial name for the plant *Harpagophytum procumbens* (“Devil's Claw”)—as a purported remedy for arthritis and chronic pain. An independent scientific analysis conducted at the New York Botanical Garden (“NYBG”) concluded that your company sold a devil's claw supplement derived, in whole or in part, from a different, cheaper species that is considered less desirable: *Harpagophytum zeyheri* (the “Substitute Plant”). This would violate several provisions of federal and New York law. *See, e.g.*, 21 U.S.C. §§ 331(a), 342-343; N.Y. Agric. & Mkts. Law § 199-a; N.Y. Gen. Bus. Law § 349.

Scientists affiliated with NYBG, a leading botanical research center, used a DNA barcoding technique to identify the relevant plant source for a range of supplements labeled as containing devil's claw or devil's claw extract.¹ The NYBG study revealed widespread

¹ DNA barcoding is a sophisticated genetic technique that relies on short, unique sequences of DNA to identify the source of plant or animal material. To carry out the NYBG study, researchers first identified unique mini-barcodes, specifically focused on the *psbAtrnH* genetic marker, to distinguish between the two *Harpagophytum* species. The study analyzed 23 supplements labeled as containing devil's claw or a devil's claw extract, including both single-ingredient supplements and complex mixtures. Five of the tested supplements were produced by non-U.S. companies and labeled for overseas sale, and are therefore excluded from the results discussed in this letter. Of the 18 supplements labeled for sale in the United States, NYBG extracted identifiable DNA from all but two of the products. (Only one of the two is labeled as an “extract” in the “supplement facts” panel.)

substitution and adulteration; of 16 U.S. made devil's claw supplements where the relevant plant source could be identified—produced by 14 separate companies, including large and small firms—**100%** were found to contain the Substitute Plant, either alone (81%) or in combination with Devil's Claw (19%). According to subpoenaed documents, this included a product sold by your company under the Vitacost brand as "Devil's Claw," Lot No. 132580 (the "Tested Lot"). Your product's label expressly identified the species as "*Harpagophytum procumbens*," i.e. as Devil's Claw. The NYBG study concluded that your company's product instead contained the Substitute Plant.

Because of the implications for consumers, we are contacting your company prior to publication of the NYBG study. This analysis, however, is far from the first to draw attention to serious quality control and compliance problems in the supplement industry. Nor is it the first red flag indicating fraud, misidentification, or other serious problems in the supply chain for Devil's Claw, a popular and scarce plant indigenous to the Kalahari Desert; reports of raw material suppliers mixing or replacing dried Devil's Claw root tubers with the similar-looking dried root tubers of the Substitute Plant—a cheaper plant in the same genus—are common. In this context, the results of the NYBG study are especially troubling; they suggest an industry-wide failure to take necessary steps to comply with law and ensure the accuracy of claims concerning the quality and authenticity of the supplements marketed to consumers.

As a matter of commerce, science, and law, Devil's Claw (*Harpagophytum procumbens*) and the Substitute Plant (*Harpagophytum zeyheri*) are distinct species:

- **Commercially**, Devil's Claw is preferred in virtually all respects, is scarcer, and commands a higher market price. After contacting several suppliers, the Office of the New York Attorney General received price quotes for Devil's Claw root that were *two- to three-times higher* than a similar quote for the Substitute Plant.
- **Scientifically**, the two plants are separate species that can be easily distinguished in the wild. Herbalists link the purported therapeutic properties of Devil's Claw—which are not generally accepted in the medical community or approved by the FDA—to certain naturally-occurring chemical compounds, specifically iridoid glycosides. These chemicals tend to occur naturally in Devil's Claw at much higher concentrations. They also appear in different ratios in the two plants, and at least one chemically potent phenol glycoside in Devil's Claw (6-acetylacteoside) is missing from the Substitute Plant. Moreover, supplements derived from the Substitute Plant—even those "standardized" to deliver a promised percentage of certain iridoid glycosides—are also likely to expose users to other chemicals that are either absent from Devil's Claw or present at lower concentrations.²

² Certain overseas jurisdictions allow the Substitute Plant to be sold as part of the same product as Devil's Claw. This approach has been criticized in the scientific literature due, in part, to the distinct chemical profiles of the two plants and the lack of evidence that the two are pharmacologically equivalent. See, e.g., Nontobeko P. Mncwangi, et al., *What the devil is in your phytomedicine? Exploring species substitution in Harpagophytum through chemometric modeling of ¹H-NMR and UHPLC-MS datasets*, 106 *Phytochemistry* 104-115 (October 2014) ("[O]ur results clearly demonstrate a phytochemical disparity between the two species which may impact on their biological properties. . . . The chemometric analysis results showed that the two species are not chemically equivalent, particularly, that

- Legally, the 1992 Edition of Herbs of Commerce supplies the list of plants that may be sold in the United States commercially under particular common names. 21 C.F.R. 101.4(h).³ The relevant definition—which was reaffirmed in the more recent edition—defines devil’s claw as *Harpagophytum procumbens*, *i.e.* as Devil’s Claw. Representing any plant other than Devil’s Claw as “devil’s claw” is inconsistent with the definition codified in the Herbs of Commerce and is misleading as a matter of law. Misapplying the common name is all the more problematic where, as here, the scientific name of the non-standard species appears nowhere on the label.

Nor are we convinced that the Substitute Plant would be lawful for sale in New York or elsewhere in the United States under its proper scientific name, *i.e.* as *Harpagophytum zeyheri*. Under federal law, a manufacturer may legally sell a “new dietary ingredient”—or an ingredient that was first marketed in the United States after October 15, 1994—if it was (i) used as a source of food; or (ii) submitted to the federal Food and Drug Administration as part of a new dietary ingredient notification at least 75 days prior to initial sale. *See* 21 U.S.C. § 350b; 21 U.S.C. § 331(a); *see also* FDA Draft Guidance on New Dietary Ingredient Notifications, Docket No. FDA-2011-D-0376 76, Fed. Reg. 39111 (July 5, 2011). First, Devil’s Claw has long been marketed in the United States, including as “grapple” and “harpagophytum root.” We have seen no comparable evidence establishing that the Substitute Plant, *i.e.* *Harpagophytum zeyheri*, was sold in the United States prior to 1994, except as an unwanted adulterant.⁴ Second, the Substitute Plant appears to satisfy neither of the requirements for new dietary ingredients.⁵

In connection with an investigation arising under N.Y. Exec. Law § 63(12), N.Y. Gen. Bus. Law § 349, N.Y. Agric. & Mkts. Law § 8, and other authorities, we therefore request a detailed, written response to this letter within 10 business days. In addition to offering you an opportunity to respond to, or dispute any of the analysis above, we ask that your response cover the topics and incorporate the materials identified in the attached Appendix, including but not limited to:

- (i) The methodology and results of any testing your company performs or has performed by a third party on the Tested Lot to independently verify the results of the NYBG study;
- (ii) Your company’s plans for identifying and, where appropriate, recalling any and all non-complying devil’s claw supplements;

harpagoside is not always present in *H. zeyheri*, suggesting that the therapeutic outcome may be different, thus they should not be used interchangeably until pharmacological equivalence has been confirmed.”)

³ Herbs of Commerce seeks to avoid confusion in the herbal supplements marketplace by applying “a single common name in trade . . . to only one botanical name.” *Id.* at I (introduction). The common name “devil’s claw” perfectly illustrates the problem. Overseas and in non-commercial settings, that name has been used loosely to refer to numerous species, including the Substitute Plant as well as other wholly unrelated plants like *Pisonia aculeate*, *Proboscidea altheaefolia*, and *Senegalia greggii*.

⁴ To the contrary, various sources dating back many years identify the Substitute Plant as an unwanted adulterant, which was not legally exported internationally until European standards were loosened in 2003.

⁵ Like many traditional herbal supplements, Devil’s Claw may be administered orally, including as a tea. This does not convert it or the Substitute Plant into a source of food for purposes of the new dietary ingredient requirements.

- (iii) Your company's proposal for identifying and, where appropriate, compensating any defrauded or otherwise harmed consumers; and
- (iv) Any and all new reforms your company will implement to ensure the quality and authenticity of the herbal supplements it manufactures or distributes, including new analytical testing methods.

Notwithstanding this response, we further advise you to preserve and retain any and all documents and communications concerning the subjects addressed in this letter, including but not limited to: (i) the sourcing of ingredients for devil's claw and other herbal dietary supplements; (ii) the measures used to verify the reliability of suppliers of devil's claw and other herbal ingredients; (iii) quality control for devil's claw and other herbal dietary supplements, including awareness of misidentification of herbal products and financially motivated adulteration, with respect to raw materials or finished products; (iv) the labeling and marketing of devil's claw and other herbal supplements; and (v) the manufacturing protocols and testing methods employed to ensure the accuracy of all label and marketing claims relating to the identity, purity, potency, or other characteristics of devil's claw and other herbal supplements.

Please do not hesitate to reach out to our office with any questions or concerns.

Respectfully,



Simon G. Brandler
Senior Advisor & Special Counsel
212-416-6544 / Simon.Brandler@ag.ny.gov

CC Christine Wheatley, Secretary and General Counsel

APPENDIX

Request for Additional Documentation and Information

With your response, please furnish the following information or documentation:

- (1) For each shipment of ingredients or products your company received since January 1, 2012 that were purportedly derived, in whole or in part, from Devil's Claw and/or the Substitute Plant (the "DC Ingredients"):
 - a. The name, address, telephone number, email address, and other contact information for the supplier from whom your company obtained the shipment;
 - b. The supplier's descriptions of the content of the shipment, as they appeared on order forms, packing slips, contracts, and other written materials;
 - c. The date your company received the shipment;
 - d. The address where your company received the shipment;
 - e. The form in which the DC Ingredients arrived (e.g. powdered extract, cut-and-dried tubers, powdered whole herbs, etc.);
 - f. The address or addresses of the manufacturing facilities that produced any finished supplements containing the DC Ingredients;
 - g. The volume in kilograms of DC Ingredients received;
 - h. The total price your company paid for the DC Ingredients in the shipment in U.S. dollars; and
 - i. Copies of all product labels (front and back) for all supplements produced using the DC Ingredients in that shipment.
- (2) Copies of all audits, reviews, or other documents or communications prepared by your company or a third party to assess the reliability of any supplier who sold DC Ingredients to your company from January 1, 2012 to the present, and a description of any other verification measures not reflected in such documents and communications;
- (3) Copies of all documents and communications, including but not limited to order forms, contracts, packing slips, contracts, correspondence, or other written or electronic materials, concerning the shipment or shipments of DC Ingredients used in manufacturing the Tested Lot;
- (4) A complete description of the methodology and copies of the results of any testing or analyses your company performed or had performed from January 1, 2012 to the present on DC Ingredients or on finished dietary supplements containing DC Ingredients for identity, potency, purity, or any other characteristic, along with a

statement indicating whether any such testing could distinguish between Devil's Claw and the Substitute Plant;

- (5) A complete description of the testing or other measures your company undertook, is undertaking, or intends to undertake to determine the degree to which the products it sold since January 1, 2012 purporting to contain DC Ingredients were adulterated or misbranded, including but not limited to the Tested Lot;
- (6) The results of any and all testing described in response to Item 5 or of any other testing performed on the Tested Lot;
- (7) Copies of any and all documents or communications concerning the Tested Lot or its sale;
- (8) Copies of all documents and communications your company sent to, received from, or exchanged with any employee or agent of the federal Food and Drug Administration ("FDA") since January 1, 2012 concerning inspections of the company facilities identified in response to Item 1(f) above, including but not limited to Form 483s and your company's response thereto.
- (9) For each year from January 1, 2012 to the present, the total annual revenue or, for 2015, the year-to-date revenue your company received respectively from the sale of dietary supplements containing DC Ingredients in (i) retail sales in New York State; (ii) Internet sales to New York State residents; and (iii) the United States overall;
- (10) A proposal for identifying and, as appropriate, compensating any purchasers of devil's claw supplements your company manufactured who may have received adulterated or misbranded products; and
- (11) A complete description of improvements, safeguards, or reforms your company will implement to avoid adulteration or misbranding of herbal dietary supplements in the future, including but not limited to testing or other measures to detect and prevent the adulteration or misbranding of supplement's containing DC Ingredients.



STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

EXECUTIVE DIVISION
SPECIAL COUNSEL

September 9, 2015

Gregory L. Probert
Chairman and Chief Executive Officer
Nature's Sunshine Products, Inc.
2500 West Executive Parkway, Suite 100
Lehi, UT 84043

Re: Misbranding/Adulteration of Devil's Claw Dietary Supplements

Dear Mr. Probert,

This letter constitutes a demand that Nature's Sunshine Products, Inc. cease and desist from the marketing, distribution, or sale of misbranded or adulterated devil's claw dietary supplements. For the reasons set forth below, we advise you to furnish the requested documentation and take immediate steps to identify and compensate any consumers who purchased misbranded or adulterated products.

The dietary supplements industry markets devil's claw—the commercial name for the plant *Harpagophytum procumbens* (“Devil's Claw”)—as a purported remedy for arthritis and chronic pain. An independent scientific analysis conducted at the New York Botanical Garden (“NYBG”) concluded that your company sold a devil's claw supplement derived, in whole or in part, from a different, cheaper species that is considered less desirable: *Harpagophytum zeyheri* (the “Substitute Plant”). This would violate several provisions of federal and New York law. *See, e.g.,* 21 U.S.C. §§ 331(a), 342-343; N.Y. Agric. & Mkts. Law § 199-a; N.Y. Gen. Bus. Law § 349.

Scientists affiliated with NYBG, a leading botanical research center, used a DNA barcoding technique to identify the relevant plant source for a range of supplements labeled as containing devil's claw or devil's claw extract.¹ The NYBG study revealed widespread

¹ DNA barcoding is a sophisticated genetic technique that relies on short, unique sequences of DNA to identify the source of plant or animal material. To carry out the NYBG study, researchers first identified unique mini-barcodes, specifically focused on the *psbAtrnH* genetic marker, to distinguish between the two *Harpagophytum* species. The study analyzed 23 supplements labeled as containing devil's claw or a devil's claw extract, including both single-ingredient supplements and complex mixtures. Five of the tested supplements were produced by non-U.S. companies and labeled for overseas sale, and are therefore excluded from the results discussed in this letter. Of the 18 supplements labeled for sale in the United States, NYBG extracted identifiable DNA from all but two of the products. (Only one of the two is labeled as an “extract” in the “supplement facts” panel.)

substitution and adulteration; of 16 U.S. made devil's claw supplements where the relevant plant source could be identified—produced by 14 separate companies, including large and small firms—**100%** were found to contain the Substitute Plant, either alone (81%) or in combination with Devil's Claw (19%). According to subpoenaed documents, this included a product sold by your company as "Devil's Claw," Lot No. 10784203 (the "Tested Lot"). Your product's label expressly identified the species as "*Harpagophytum procumbens*," *i.e.* as Devil's Claw. The NYBG study concluded that your company's product instead contained the Substitute Plant.

Because of the implications for consumers, we are contacting your company prior to publication of the NYBG study. This analysis, however, is far from the first to draw attention to serious quality control and compliance problems in the supplement industry. Nor is it the first red flag indicating fraud, misidentification, or other serious problems in the supply chain for Devil's Claw, a popular and scarce plant indigenous to the Kalahari Desert; reports of raw material suppliers mixing or replacing dried Devil's Claw root tubers with the similar-looking dried root tubers of the Substitute Plant—a cheaper plant in the same genus—are common. In this context, the results of the NYBG study are especially troubling; they suggest an industry-wide failure to take necessary steps to comply with law and ensure the accuracy of claims concerning the quality and authenticity of the supplements marketed to consumers.

As a matter of commerce, science, and law, Devil's Claw (*Harpagophytum procumbens*) and the Substitute Plant (*Harpagophytum zeyheri*) are distinct species:

- **Commercially**, Devil's Claw is preferred in virtually all respects, is scarcer, and commands a higher market price. After contacting several suppliers, the Office of the New York Attorney General received price quotes for Devil's Claw root that were *two- to three-times higher* than a similar quote for the Substitute Plant.
- **Scientifically**, the two plants are separate species that can be easily distinguished in the wild. Herbalists link the purported therapeutic properties of Devil's Claw—which are not generally accepted in the medical community or approved by the FDA—to certain naturally-occurring chemical compounds, specifically iridoid glycosides. These chemicals tend to occur naturally in Devil's Claw at much higher concentrations. They also appear in different ratios in the two plants, and at least one chemically potent phenol glycoside in Devil's Claw (6-acetylacteoside) is missing from the Substitute Plant. Moreover, supplements derived from the Substitute Plant—even those "standardized" to deliver a promised percentage of certain iridoid glycosides—are also likely to expose users to other chemicals that are either absent from Devil's Claw or present at lower concentrations.²

² Certain overseas jurisdictions allow the Substitute Plant to be sold as part of the same product as Devil's Claw. This approach has been criticized in the scientific literature due, in part, to the distinct chemical profiles of the two plants and the lack of evidence that the two are pharmacologically equivalent. See, e.g., Nontobeko P. Mncwangi, et al., *What the devil is in your phytomedicine? Exploring species substitution in Harpagophytum through chemometric modeling of ¹H-NMR and UHPLC-MS datasets*, 106 *Phytochemistry* 104-115 (October 2014) ("[O]ur results clearly demonstrate a phytochemical disparity between the two species which may impact on their biological properties. . . . The chemometric analysis results showed that the two species are not chemically equivalent, particularly, that harpagoside is not always present in *H. zeyheri*, suggesting that the therapeutic outcome may be different, thus they should not be used interchangeably until pharmacological equivalence has been confirmed.")

- Legally, the 1992 Edition of Herbs of Commerce supplies the list of plants that may be sold in the United States commercially under particular common names. 21 C.F.R. 101.4(h).³ The relevant definition—which was reaffirmed in the more recent edition—defines devil’s claw as *Harpagophytum procumbens*, i.e. as Devil’s Claw. Representing any plant other than Devil’s Claw as “devil’s claw” is inconsistent with the definition codified in the Herbs of Commerce and is misleading as a matter of law. Misapplying the common name is all the more problematic where, as here, the scientific name of the non-standard species appears nowhere on the label.

Nor are we convinced that the Substitute Plant would be lawful for sale in New York or elsewhere in the United States under its proper scientific name, i.e. as *Harpagophytum zeyheri*. Under federal law, a manufacturer may legally sell a “new dietary ingredient”—or an ingredient that was first marketed in the United States after October 15, 1994—if it was (i) used as a source of food; or (ii) submitted to the federal Food and Drug Administration as part of a new dietary ingredient notification at least 75 days prior to initial sale. See 21 U.S.C. § 350b; 21 U.S.C. § 331(a); see also FDA Draft Guidance on New Dietary Ingredient Notifications, Docket No. FDA-2011-D-0376 76, Fed. Reg. 39111 (July 5, 2011). First, Devil’s Claw has long been marketed in the United States, including as “grapple” and “harpagophytum root.” We have seen no comparable evidence establishing that the Substitute Plant, i.e. *Harpagophytum zeyheri*, was sold in the United States prior to 1994, except as an unwanted adulterant.⁴ Second, the Substitute Plant appears to satisfy neither of the requirements for new dietary ingredients.⁵

In connection with an investigation arising under N.Y. Exec. Law § 63(12), N.Y. Gen. Bus. Law § 349, N.Y. Agric. & Mkts. Law § 8, and other authorities, we therefore request a detailed, written response to this letter within 10 business days. In addition to offering you an opportunity to respond to, or dispute any of the analysis above, we ask that your response cover the topics and incorporate the materials identified in the attached Appendix, including but not limited to:

- (i) The methodology and results of any testing your company performs or has performed by a third party on the Tested Lot to independently verify the results of the NYBG study;
- (ii) Your company’s plans for identifying and, where appropriate, recalling any and all non-complying devil’s claw supplements;

³ Herbs of Commerce seeks to avoid confusion in the herbal supplements marketplace by applying “a single common name in trade . . . to only one botanical name.” *Id.* at I (introduction). The common name “devil’s claw” perfectly illustrates the problem. Overseas and in non-commercial settings, that name has been used loosely to refer to numerous species, including the Substitute Plant as well as other wholly unrelated plants like *Pisonia aculeate*, *Proboscidea altheaefolia*, and *Senegalia greggii*.

⁴ To the contrary, various sources dating back many years identify the Substitute Plant as an unwanted adulterant, which was not legally exported internationally until European standards were loosened in 2003.

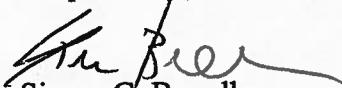
⁵ Like many traditional herbal supplements, Devil’s Claw may be administered orally, including as a tea. This does not convert it or the Substitute Plant into a source of food for purposes of the new dietary ingredient requirements.

- (iii) Your company's proposal for identifying and, where appropriate, compensating any defrauded or otherwise harmed consumers; and
- (iv) Any and all new reforms your company will implement to ensure the quality and authenticity of the herbal supplements it manufactures or distributes, including new analytical testing methods.

Notwithstanding this response, we further advise you to preserve and retain any and all documents and communications concerning the subjects addressed in this letter, including but not limited to: (i) the sourcing of ingredients for devil's claw and other herbal dietary supplements; (ii) the measures used to verify the reliability of suppliers of devil's claw and other herbal ingredients; (iii) quality control for devil's claw and other herbal dietary supplements, including awareness of misidentification of herbal products and financially motivated adulteration, with respect to raw materials or finished products; (iv) the labeling and marketing of devil's claw and other herbal supplements; and (v) the manufacturing protocols and testing methods employed to ensure the accuracy of all label and marketing claims relating to the identity, purity, potency, or other characteristics of devil's claw and other herbal supplements.

Please do not hesitate to reach out to our office with any questions or concerns.

Respectfully,



Simon G. Brandler
Senior Advisor & Special Counsel
212-416-6544 / Simon.Brandler@ag.ny.gov

CC Richard Strulson, General Counsel

APPENDIX

Request for Additional Documentation and Information

With your response, please furnish the following information or documentation:

- (1) For each shipment of ingredients or products your company received since January 1, 2012 that were purportedly derived, in whole or in part, from Devil's Claw and/or the Substitute Plant (the "DC Ingredients"):
 - a. The name, address, telephone number, email address, and other contact information for the supplier from whom your company obtained the shipment;
 - b. The supplier's descriptions of the content of the shipment, as they appeared on order forms, packing slips, contracts, and other written materials;
 - c. The date your company received the shipment;
 - d. The address where your company received the shipment;
 - e. The form in which the DC Ingredients arrived (e.g. powdered extract, cut-and-dried tubers, powdered whole herbs, etc.);
 - f. The address or addresses of the manufacturing facilities that produced any finished supplements containing the DC Ingredients;
 - g. The volume in kilograms of DC Ingredients received;
 - h. The total price your company paid for the DC Ingredients in the shipment in U.S. dollars; and
 - i. Copies of all product labels (front and back) for all supplements produced using the DC Ingredients in that shipment.
- (2) Copies of all audits, reviews, or other documents or communications prepared by your company or a third party to assess the reliability of any supplier who sold DC Ingredients to your company from January 1, 2012 to the present, and a description of any other verification measures not reflected in such documents and communications;
- (3) Copies of all documents and communications, including but not limited to order forms, contracts, packing slips, contracts, correspondence, or other written or electronic materials, concerning the shipment or shipments of DC Ingredients used in manufacturing the Tested Lot;
- (4) A complete description of the methodology and copies of the results of any testing or analyses your company performed or had performed from January 1, 2012 to the present on DC Ingredients or on finished dietary supplements containing DC Ingredients for identity, potency, purity, or any other characteristic, along with a

statement indicating whether any such testing could distinguish between Devil's Claw and the Substitute Plant;

- (5) A complete description of the testing or other measures your company undertook, is undertaking, or intends to undertake to determine the degree to which the products it sold since January 1, 2012 purporting to contain DC Ingredients were adulterated or misbranded, including but not limited to the Tested Lot;
- (6) The results of any and all testing described in response to Item 5 or of any other testing performed on the Tested Lot;
- (7) Copies of any and all documents or communications concerning the Tested Lot or its sale;
- (8) Copies of all documents and communications your company sent to, received from, or exchanged with any employee or agent of the federal Food and Drug Administration ("FDA") since January 1, 2012 concerning inspections of the company facilities identified in response to Item 1(f) above, including but not limited to Form 483s and your company's response thereto.
- (9) For each year from January 1, 2012 to the present, the total annual revenue or, for 2015, the year-to-date revenue your company received respectively from the sale of dietary supplements containing DC Ingredients in (i) retail sales in New York State; (ii) Internet sales to New York State residents; and (iii) the United States overall;
- (10) A proposal for identifying and, as appropriate, compensating any purchasers of devil's claw supplements your company manufactured who may have received adulterated or misbranded products; and
- (11) A complete description of improvements, safeguards, or reforms your company will implement to avoid adulteration or misbranding of herbal dietary supplements in the future, including but not limited to testing or other measures to detect and prevent the adulteration or misbranding of supplement's containing DC Ingredients.



STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

EXECUTIVE DIVISION
SPECIAL COUNSEL

September 9, 2015

Steve Cahillane
President and CEO
NBTY, Inc.
2100 Smithtown Ave
Ronkonkoma, NY 11779

Re: Misbranding/Adulteration of Devil's Claw Dietary Supplements

Dear Mr. Cahillane,

This letter constitutes a demand that NBTY, Inc. cease and desist from the marketing, distribution, or sale of misbranded or adulterated devil's claw dietary supplements. For the reasons set forth below, we advise you to furnish the requested documentation and take immediate steps to identify and compensate any consumers who purchased misbranded or adulterated products.

The dietary supplements industry markets devil's claw—the commercial name for the plant *Harpagophytum procumbens* (“Devil's Claw”)—as a purported remedy for arthritis and chronic pain. An independent scientific analysis conducted at the New York Botanical Garden (“NYBG”) concluded that your company sold a devil's claw supplement derived, in whole or in part, from a different, cheaper species that is considered less desirable: *Harpagophytum zeyheri* (the “Substitute Plant”). This would violate several provisions of federal and New York law. *See, e.g.*, 21 U.S.C. §§ 331(a), 342-343; N.Y. Agric. & Mkts. Law § 199-a; N.Y. Gen. Bus. Law § 349.

Scientists affiliated with NYBG, a leading botanical research center, used a DNA barcoding technique to identify the relevant plant source for a range of supplements labeled as containing devil's claw or devil's claw extract.¹ The NYBG study revealed widespread

¹ DNA barcoding is a sophisticated genetic technique that relies on short, unique sequences of DNA to identify the source of plant or animal material. To carry out the NYBG study, researchers first identified unique mini-barcodes, specifically focused on the *psbAtrnH* genetic marker, to distinguish between the two *Harpagophytum* species. The study analyzed 23 supplements labeled as containing devil's claw or a devil's claw extract, including both single-ingredient supplements and complex mixtures. Five of the tested supplements were produced by non-U.S. companies and labeled for overseas sale, and are therefore excluded from the results discussed in this letter. Of the 18 supplements labeled for sale in the United States, NYBG extracted identifiable DNA from all but two of the products. (Only one of the two is labeled as an “extract” in the “supplement facts” panel.)

substitution and adulteration; of 16 U.S. made devil's claw supplements where the relevant plant source could be identified—produced by 14 separate companies, including large and small firms—100% were found to contain the Substitute Plant, either alone (81%) or in combination with Devil's Claw (19%). According to subpoenaed documents, this included a product sold by your company under its Puritan's Pride brand as "Devil's Claw," Lot No. 749712-01 (the "Tested Lot"). Your product's label expressly identified the species as "*Harpagophytum procumbens*," *i.e.* as Devil's Claw. The NYBG study concluded that your company's Devil's Claw product also contained the Substitute Plant.

Because of the implications for consumers, we are contacting your company prior to publication of the NYBG study. This analysis, however, is far from the first to draw attention to serious quality control and compliance problems in the supplement industry. Nor is it the first red flag indicating fraud, misidentification, or other serious problems in the supply chain for Devil's Claw, a popular and scarce plant indigenous to the Kalahari Desert; reports of raw material suppliers mixing or replacing dried Devil's Claw root tubers with the similar-looking dried root tubers of the Substitute Plant—a cheaper plant in the same genus—are common. In this context, the results of the NYBG study are especially troubling; they suggest an industry-wide failure to take necessary steps to comply with law and ensure the accuracy of claims concerning the quality and authenticity of the supplements marketed to consumers.

As a matter of commerce, science, and law, Devil's Claw (*Harpagophytum procumbens*) and the Substitute Plant (*Harpagophytum zeyheri*) are distinct species:

- Commercially, Devil's Claw is preferred in virtually all respects, is scarcer, and commands a higher market price. After contacting several suppliers, the Office of the New York Attorney General received price quotes for Devil's Claw root that were *two- to three-times higher* than a similar quote for the Substitute Plant.
- Scientifically, the two plants are separate species that can be easily distinguished in the wild. Herbalists link the purported therapeutic properties of Devil's Claw—which are not generally accepted in the medical community or approved by the FDA—to certain naturally-occurring chemical compounds, specifically iridoid glycosides. These chemicals tend to occur naturally in Devil's Claw at much higher concentrations. They also appear in different ratios in the two plants, and at least one chemically potent phenol glycoside in Devil's Claw (6-acetylacteoside) is missing from the Substitute Plant. Moreover, supplements derived from the Substitute Plant—even those "standardized" to deliver a promised percentage of certain iridoid glycosides—are also likely to expose users to other chemicals that are either absent from Devil's Claw or present at lower concentrations.²

² Certain overseas jurisdictions allow the Substitute Plant to be sold as part of the same product as Devil's Claw. This approach has been criticized in the scientific literature due, in part, to the distinct chemical profiles of the two plants and the lack of evidence that the two are pharmacologically equivalent. *See, e.g.,* Nontobeko P. Mncwangi, et al., *What the devil is in your phytomedicine? Exploring species substitution in Harpagophytum through chemometric modeling of ¹H-NMR and UHPLC-MS datasets*, 106 *Phytochemistry* 104-115 (October 2014) ("[O]ur results clearly demonstrate a phytochemical disparity between the two species which may impact on their biological properties. . . . The chemometric analysis results showed that the two species are not chemically equivalent, particularly, that

- Legally, the 1992 Edition of Herbs of Commerce supplies the list of plants that may be sold in the United States commercially under particular common names. 21 C.F.R. 101.4(h).³ The relevant definition—which was reaffirmed in the more recent edition—defines devil’s claw as *Harpagophytum procumbens*, *i.e.* as Devil’s Claw. Representing any plant other than Devil’s Claw as “devil’s claw” is inconsistent with the definition codified in the Herbs of Commerce and is misleading as a matter of law. Misapplying the common name is all the more problematic where, as here, the scientific name of the non-standard species appears nowhere on the label.

Nor are we convinced that the Substitute Plant would be lawful for sale in New York or elsewhere in the United States under its proper scientific name, *i.e.* as *Harpagophytum zeyheri*. Under federal law, a manufacturer may legally sell a “new dietary ingredient”—or an ingredient that was first marketed in the United States after October 15, 1994—if it was (i) used as a source of food; or (ii) submitted to the federal Food and Drug Administration as part of a new dietary ingredient notification at least 75 days prior to initial sale. *See* 21 U.S.C. § 350b; 21 U.S.C. § 331(a); *see also* FDA Draft Guidance on New Dietary Ingredient Notifications, Docket No. FDA-2011-D-0376 76, Fed. Reg. 39111 (July 5, 2011). First, Devil’s Claw has long been marketed in the United States, including as “grapple” and “harpagophytum root.” We have seen no comparable evidence establishing that the Substitute Plant, *i.e.* *Harpagophytum zeyheri*, was sold in the United States prior to 1994, except as an unwanted adulterant.⁴ Second, the Substitute Plant appears to satisfy neither of the requirements for new dietary ingredients.⁵

In connection with an investigation arising under N.Y. Exec. Law § 63(12), N.Y. Gen. Bus. Law § 349, N.Y. Agric. & Mkts. Law § 8, and other authorities, we therefore request a detailed, written response to this letter within 10 business days. In addition to offering you an opportunity to respond to, or dispute any of the analysis above, we ask that your response cover the topics and incorporate the materials identified in the attached Appendix, including but not limited to:

- (i) The methodology and results of any testing your company performs or has performed by a third party on the Tested Lot to independently verify the results of the NYBG study;
- (ii) Your company’s plans for identifying and, where appropriate, recalling any and all non-complying devil’s claw supplements;

harpagoside is not always present in *H. zeyheri*, suggesting that the therapeutic outcome may be different, thus they should not be used interchangeably until pharmacological equivalence has been confirmed.”)

³ Herbs of Commerce seeks to avoid confusion in the herbal supplements marketplace by applying “a single common name in trade . . . to only one botanical name.” *Id.* at I (introduction). The common name “devil’s claw” perfectly illustrates the problem. Overseas and in non-commercial settings, that name has been used loosely to refer to numerous species, including the Substitute Plant as well as other wholly unrelated plants like *Pisonia aculeate*, *Proboscidea altheaefolia*, and *Senegalia greggii*.

⁴ To the contrary, various sources dating back many years identify the Substitute Plant as an unwanted adulterant, which was not legally exported internationally until European standards were loosened in 2003.

⁵ Like many traditional herbal supplements, Devil’s Claw may be administered orally, including as a tea. This does not convert it or the Substitute Plant into a source of food for purposes of the new dietary ingredient requirements.

- (iii) Your company's proposal for identifying and, where appropriate, compensating any defrauded or otherwise harmed consumers; and
- (iv) Any and all new reforms your company will implement to ensure the quality and authenticity of the herbal supplements it manufactures or distributes, including new analytical testing methods.

Notwithstanding this response, we further advise you to preserve and retain any and all documents and communications concerning the subjects addressed in this letter, including but not limited to: (i) the sourcing of ingredients for devil's claw and other herbal dietary supplements; (ii) the measures used to verify the reliability of suppliers of devil's claw and other herbal ingredients; (iii) quality control for devil's claw and other herbal dietary supplements, including awareness of misidentification of herbal products and financially motivated adulteration, with respect to raw materials or finished products; (iv) the labeling and marketing of devil's claw and other herbal supplements; and (v) the manufacturing protocols and testing methods employed to ensure the accuracy of all label and marketing claims relating to the identity, purity, potency, or other characteristics of devil's claw and other herbal supplements.

Please do not hesitate to reach out to our office with any questions or concerns.

Respectfully,



Simon G. Brandler
Senior Advisor & Special Counsel
212-416-6544 / Simon.Brandler@ag.ny.gov

CC Christopher S. Brennan, General Counsel
Peter Shapiro, President, Puritan's Pride
Patricia Lynch, Patricia Lynch Associates

APPENDIX

Request for Additional Documentation and Information

With your response, please furnish the following information or documentation:

- (1) For each shipment of ingredients or products your company received since January 1, 2012 that were purportedly derived, in whole or in part, from Devil's Claw and/or the Substitute Plant (the "DC Ingredients"):
 - a. The name, address, telephone number, email address, and other contact information for the supplier from whom your company obtained the shipment;
 - b. The supplier's descriptions of the content of the shipment, as they appeared on order forms, packing slips, contracts, and other written materials;
 - c. The date your company received the shipment;
 - d. The address where your company received the shipment;
 - e. The form in which the DC Ingredients arrived (e.g. powdered extract, cut-and-dried tubers, powdered whole herbs, etc.);
 - f. The address or addresses of the manufacturing facilities that produced any finished supplements containing the DC Ingredients;
 - g. The volume in kilograms of DC Ingredients received;
 - h. The total price your company paid for the DC Ingredients in the shipment in U.S. dollars; and
 - i. Copies of all product labels (front and back) for all supplements produced using the DC Ingredients in that shipment.
- (2) Copies of all audits, reviews, or other documents or communications prepared by your company or a third party to assess the reliability of any supplier who sold DC Ingredients to your company from January 1, 2012 to the present, and a description of any other verification measures not reflected in such documents and communications;
- (3) Copies of all documents and communications, including but not limited to order forms, contracts, packing slips, contracts, correspondence, or other written or electronic materials, concerning the shipment or shipments of DC Ingredients used in manufacturing the Tested Lot;
- (4) A complete description of the methodology and copies of the results of any testing or analyses your company performed or had performed from January 1, 2012 to the present on DC Ingredients or on finished dietary supplements containing DC Ingredients for identity, potency, purity, or any other characteristic, along with a

statement indicating whether any such testing could distinguish between Devil's Claw and the Substitute Plant;

- (5) A complete description of the testing or other measures your company undertook, is undertaking, or intends to undertake to determine the degree to which the products it sold since January 1, 2012 purporting to contain DC Ingredients were adulterated or misbranded, including but not limited to the Tested Lot;
- (6) The results of any and all testing described in response to Item 5 or of any other testing performed on the Tested Lot;
- (7) Copies of any and all documents or communications concerning the Tested Lot or its sale;
- (8) Copies of all documents and communications your company sent to, received from, or exchanged with any employee or agent of the federal Food and Drug Administration ("FDA") since January 1, 2012 concerning inspections of the company facilities identified in response to Item 1(f) above, including but not limited to Form 483s and your company's response thereto.
- (9) For each year from January 1, 2012 to the present, the total annual revenue or, for 2015, the year-to-date revenue your company received respectively from the sale of dietary supplements containing DC Ingredients in (i) retail sales in New York State; (ii) Internet sales to New York State residents; and (iii) the United States overall;
- (10) A proposal for identifying and, as appropriate, compensating any purchasers of devil's claw supplements your company manufactured who may have received adulterated or misbranded products; and
- (11) A complete description of improvements, safeguards, or reforms your company will implement to avoid adulteration or misbranding of herbal dietary supplements in the future, including but not limited to testing or other measures to detect and prevent the adulteration or misbranding of supplement's containing DC Ingredients.



STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

EXECUTIVE DIVISION
SPECIAL COUNSEL

September 9, 2015

Jim Emme
Chief Executive Officer
Now Foods
244 Knollwood Drive, Suite 300
Bloomington, IL 60108

Re: Misbranding/Adulteration of Devil's Claw Dietary Supplements

Dear Mr. Emme,

This letter constitutes a demand that Now Foods cease and desist from the marketing, distribution, or sale of misbranded or adulterated devil's claw dietary supplements. For the reasons set forth below, we advise you to furnish the requested documentation and take immediate steps to identify and compensate any consumers who purchased misbranded or adulterated products.

The dietary supplements industry markets devil's claw—the commercial name for the plant *Harpagophytum procumbens* (“Devil's Claw”)—as a purported remedy for arthritis and chronic pain. An independent scientific analysis conducted at the New York Botanical Garden (“NYBG”) concluded that your company sold a devil's claw supplement derived, in whole or in part, from a different, cheaper species that is considered less desirable: *Harpagophytum zeyheri* (the “Substitute Plant”). This would violate several provisions of federal and New York law. *See, e.g.,* 21 U.S.C. §§ 331(a), 342-343; N.Y. Agric. & Mkts. Law § 199-a; N.Y. Gen. Bus. Law § 349.

Scientists affiliated with NYBG, a leading botanical research center, used a DNA barcoding technique to identify the relevant plant source for a range of supplements labeled as containing devil's claw or devil's claw extract.¹ The NYBG study revealed widespread

¹ DNA barcoding is a sophisticated genetic technique that relies on short, unique sequences of DNA to identify the source of plant or animal material. To carry out the NYBG study, researchers first identified unique mini-barcodes, specifically focused on the *psbAtrnH* genetic marker, to distinguish between the two *Harpagophytum* species. The study analyzed 23 supplements labeled as containing devil's claw or a devil's claw extract, including both single-ingredient supplements and complex mixtures. Five of the tested supplements were produced by non-U.S. companies and labeled for overseas sale, and are therefore excluded from the results discussed in this letter. Of the 18 supplements labeled for sale in the United States, NYBG extracted identifiable DNA from all but two of the products. (Only one of the two is labeled as an “extract” in the “supplement facts” panel.)

substitution and adulteration; of 16 U.S. made devil's claw supplements where the relevant plant source could be identified—produced by 14 separate companies, including large and small firms—**100%** were found to contain the Substitute Plant, either alone (81%) or in combination with Devil's Claw (19%). According to subpoenaed documents, this included a product sold by your company as "Devil's Claw," Lot No. 1631880 (the "Tested Lot"). Your product's label expressly identified the species as "*Harpagophytum procumbens*," i.e. as Devil's Claw. The NYBG study concluded that your company's product instead contained the Substitute Plant.

Because of the implications for consumers, we are contacting your company prior to publication of the NYBG study. This analysis, however, is far from the first to draw attention to serious quality control and compliance problems in the supplement industry. Nor is it the first red flag indicating fraud, misidentification, or other serious problems in the supply chain for Devil's Claw, a popular and scarce plant indigenous to the Kalahari Desert; reports of raw material suppliers mixing or replacing dried Devil's Claw root tubers with the similar-looking dried root tubers of the Substitute Plant—a cheaper plant in the same genus—are common. In this context, the results of the NYBG study are especially troubling; they suggest an industry-wide failure to take necessary steps to comply with law and ensure the accuracy of claims concerning the quality and authenticity of the supplements marketed to consumers.

As a matter of commerce, science, and law, Devil's Claw (*Harpagophytum procumbens*) and the Substitute Plant (*Harpagophytum zeyheri*) are distinct species:

- **Commercially**, Devil's Claw is preferred in virtually all respects, is scarcer, and commands a higher market price. After contacting several suppliers, the Office of the New York Attorney General received price quotes for Devil's Claw root that were *two- to three-times higher* than a similar quote for the Substitute Plant.
- **Scientifically**, the two plants are separate species that can be easily distinguished in the wild. Herbalists link the purported therapeutic properties of Devil's Claw—which are not generally accepted in the medical community or approved by the FDA—to certain naturally-occurring chemical compounds, specifically iridoid glycosides. These chemicals tend to occur naturally in Devil's Claw at much higher concentrations. They also appear in different ratios in the two plants, and at least one chemically potent phenol glycoside in Devil's Claw (6-acetylacteoside) is missing from the Substitute Plant. Moreover, supplements derived from the Substitute Plant—even those "standardized" to deliver a promised percentage of certain iridoid glycosides—are also likely to expose users to other chemicals that are either absent from Devil's Claw or present at lower concentrations.²

² Certain overseas jurisdictions allow the Substitute Plant to be sold as part of the same product as Devil's Claw. This approach has been criticized in the scientific literature due, in part, to the distinct chemical profiles of the two plants and the lack of evidence that the two are pharmacologically equivalent. See, e.g., Nontobeko P. Mncwangi, et al., *What the devil is in your phytomedicine? Exploring species substitution in Harpagophytum through chemometric modeling of ¹H-NMR and UHPLC-MS datasets*, 106 *Phytochemistry* 104-115 (October 2014) ("[O]ur results clearly demonstrate a phytochemical disparity between the two species which may impact on their biological properties. . . . The chemometric analysis results showed that the two species are not chemically equivalent, particularly, that harpagoside is not always present in *H. zeyheri*, suggesting that the therapeutic outcome may be different, thus they should not be used interchangeably until pharmacological equivalence has been confirmed.")

- Legally, the 1992 Edition of Herbs of Commerce supplies the list of plants that may be sold in the United States commercially under particular common names. 21 C.F.R. 101.4(h).³ The relevant definition—which was reaffirmed in the more recent edition—defines devil’s claw as *Harpagophytum procumbens*, i.e. as Devil’s Claw. Representing any plant other than Devil’s Claw as “devil’s claw” is inconsistent with the definition codified in the Herbs of Commerce and is misleading as a matter of law. Misapplying the common name is all the more problematic where, as here, the scientific name of the non-standard species appears nowhere on the label.

Nor are we convinced that the Substitute Plant would be lawful for sale in New York or elsewhere in the United States under its proper scientific name, i.e. as *Harpagophytum zeyheri*. Under federal law, a manufacturer may legally sell a “new dietary ingredient”—or an ingredient that was first marketed in the United States after October 15, 1994—if it was (i) used as a source of food; or (ii) submitted to the federal Food and Drug Administration as part of a new dietary ingredient notification at least 75 days prior to initial sale. See 21 U.S.C. § 350b; 21 U.S.C. § 331(a); see also FDA Draft Guidance on New Dietary Ingredient Notifications, Docket No. FDA-2011-D-0376 76, Fed. Reg. 39111 (July 5, 2011). First, Devil’s Claw has long been marketed in the United States, including as “grapple” and “harpagophytum root.” We have seen no comparable evidence establishing that the Substitute Plant, i.e. *Harpagophytum zeyheri*, was sold in the United States prior to 1994, except as an unwanted adulterant.⁴ Second, the Substitute Plant appears to satisfy neither of the requirements for new dietary ingredients.⁵

In connection with an investigation arising under N.Y. Exec. Law § 63(12), N.Y. Gen. Bus. Law § 349, N.Y. Agric. & Mkts. Law § 8, and other authorities, we therefore request a detailed, written response to this letter within 10 business days. In addition to offering you an opportunity to respond to, or dispute any of the analysis above, we ask that your response cover the topics and incorporate the materials identified in the attached Appendix, including but not limited to:

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³ Herbs of Commerce seeks to avoid confusion in the herbal supplements marketplace by applying “a single common name in trade . . . to only one botanical name.” *Id.* at I (introduction). The common name “devil’s claw” perfectly illustrates the problem. Overseas and in non-commercial settings, that name has been used loosely to refer to numerous species, including the Substitute Plant as well as other wholly unrelated plants like *Pisonia aculeate*, *Proboscidea altheaefolia*, and *Senegalia greggii*.

⁴ To the contrary, various sources dating back many years identify the Substitute Plant as an unwanted adulterant, which was not legally exported internationally until European standards were loosened in 2003.

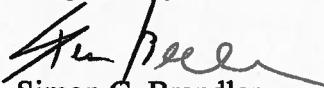
⁵ Like many traditional herbal supplements, Devil’s Claw may be administered orally, including as a tea. This does not convert it or the Substitute Plant into a source of food for purposes of the new dietary ingredient requirements.

- (iii) Your company's proposal for identifying and, where appropriate, compensating any defrauded or otherwise harmed consumers; and
- (iv) Any and all new reforms your company will implement to ensure the quality and authenticity of the herbal supplements it manufactures or distributes, including new analytical testing methods.

Notwithstanding this response, we further advise you to preserve and retain any and all documents and communications concerning the subjects addressed in this letter, including but not limited to: (i) the sourcing of ingredients for devil's claw and other herbal dietary supplements; (ii) the measures used to verify the reliability of suppliers of devil's claw and other herbal ingredients; (iii) quality control for devil's claw and other herbal dietary supplements, including awareness of misidentification of herbal products and financially motivated adulteration, with respect to raw materials or finished products; (iv) the labeling and marketing of devil's claw and other herbal supplements; and (v) the manufacturing protocols and testing methods employed to ensure the accuracy of all label and marketing claims relating to the identity, purity, potency, or other characteristics of devil's claw and other herbal supplements.

Please do not hesitate to reach out to our office with any questions or concerns.

Respectfully,



Simon G. Brandler
Senior Advisor & Special Counsel
212-416-6544 / Simon.Brandler@ag.ny.gov

CC Aaron Secrist, Director of Quality

APPENDIX

Request for Additional Documentation and Information

With your response, please furnish the following information or documentation:

- (1) For each shipment of ingredients or products your company received since January 1, 2012 that were purportedly derived, in whole or in part, from Devil's Claw and/or the Substitute Plant (the "DC Ingredients"):
 - a. The name, address, telephone number, email address, and other contact information for the supplier from whom your company obtained the shipment;
 - b. The supplier's descriptions of the content of the shipment, as they appeared on order forms, packing slips, contracts, and other written materials;
 - c. The date your company received the shipment;
 - d. The address where your company received the shipment;
 - e. The form in which the DC Ingredients arrived (e.g. powdered extract, cut-and-dried tubers, powdered whole herbs, etc.);
 - f. The address or addresses of the manufacturing facilities that produced any finished supplements containing the DC Ingredients;
 - g. The volume in kilograms of DC Ingredients received;
 - h. The total price your company paid for the DC Ingredients in the shipment in U.S. dollars; and
 - i. Copies of all product labels (front and back) for all supplements produced using the DC Ingredients in that shipment.
- (2) Copies of all audits, reviews, or other documents or communications prepared by your company or a third party to assess the reliability of any supplier who sold DC Ingredients to your company from January 1, 2012 to the present, and a description of any other verification measures not reflected in such documents and communications;
- (3) Copies of all documents and communications, including but not limited to order forms, contracts, packing slips, contracts, correspondence, or other written or electronic materials, concerning the shipment or shipments of DC Ingredients used in manufacturing the Tested Lot;
- (4) A complete description of the methodology and copies of the results of any testing or analyses your company performed or had performed from January 1, 2012 to the present on DC Ingredients or on finished dietary supplements containing DC Ingredients for identity, potency, purity, or any other characteristic, along with a

statement indicating whether any such testing could distinguish between Devil's Claw and the Substitute Plant;

- (5) A complete description of the testing or other measures your company undertook, is undertaking, or intends to undertake to determine the degree to which the products it sold since January 1, 2012 purporting to contain DC Ingredients were adulterated or misbranded, including but not limited to the Tested Lot;
- (6) The results of any and all testing described in response to Item 5 or of any other testing performed on the Tested Lot;
- (7) Copies of any and all documents or communications concerning the Tested Lot or its sale;
- (8) Copies of all documents and communications your company sent to, received from, or exchanged with any employee or agent of the federal Food and Drug Administration ("FDA") since January 1, 2012 concerning inspections of the company facilities identified in response to Item 1(f) above, including but not limited to Form 483s and your company's response thereto.
- (9) For each year from January 1, 2012 to the present, the total annual revenue or, for 2015, the year-to-date revenue your company received respectively from the sale of dietary supplements containing DC Ingredients in (i) retail sales in New York State; (ii) Internet sales to New York State residents; and (iii) the United States overall;
- (10) A proposal for identifying and, as appropriate, compensating any purchasers of devil's claw supplements your company manufactured who may have received adulterated or misbranded products; and
- (11) A complete description of improvements, safeguards, or reforms your company will implement to avoid adulteration or misbranding of herbal dietary supplements in the future, including but not limited to testing or other measures to detect and prevent the adulteration or misbranding of supplement's containing DC Ingredients.



STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

EXECUTIVE DIVISION
SPECIAL COUNSEL

September 9, 2015

Frank W. Gay II
Chief Executive Officer
Nutraceutical International Corporation
1400 Kearns Boulevard
Park City, Utah 84060

Re: Misbranding/Adulteration of Devil's Claw Dietary Supplements

Dear Mr. Gay,

This letter constitutes a demand that Nutraceutical International Corporation cease and desist from the marketing, distribution, or sale of misbranded or adulterated devil's claw dietary supplements. For the reasons set forth below, we advise you to furnish the requested documentation and take immediate steps to identify and compensate any consumers who purchased misbranded or adulterated products.

The dietary supplements industry markets devil's claw—the commercial name for the plant *Harpagophytum procumbens* (“Devil's Claw”)—as a purported remedy for arthritis and chronic pain. An independent scientific analysis conducted at the New York Botanical Garden (“NYBG”) concluded that your company sold devil's claw supplements derived, in whole or in part, from a different, cheaper species that is considered less desirable: *Harpagophytum zeyheri* (the “Substitute Plant”). This would violate several provisions of federal and New York law. *See, e.g.*, 21 U.S.C. §§ 331(a), 342-343; N.Y. Agric. & Mkts. Law § 199-a; N.Y. Gen. Bus. Law § 349.

Scientists affiliated with NYBG, a leading botanical research center, used a DNA barcoding technique to identify the relevant plant source for a range of supplements labeled as containing devil's claw or devil's claw extract.¹ The NYBG study revealed widespread

¹ DNA barcoding is a sophisticated genetic technique that relies on short, unique sequences of DNA to identify the source of plant or animal material. To carry out the NYBG study, researchers first identified unique mini-barcodes, specifically focused on the *psbAtrnH* genetic marker, to distinguish between the two *Harpagophytum* species. The study analyzed 23 supplements labeled as containing devil's claw or a devil's claw extract, including both single-ingredient supplements and complex mixtures. Five of the tested supplements were produced by non-U.S. companies and labeled for overseas sale, and are therefore excluded from the results discussed in this letter. Of the 18 supplements labeled for sale in the United States, NYBG extracted identifiable DNA from all but two of the products. (Only one of the two is labeled as an “extract” in the “supplement facts” panel.)

substitution and adulteration; of 16 U.S.-made devil's claw supplements where the relevant plant source could be identified—produced by 14 separate companies, including large and small firms—**100%** were found to contain the Substitute Plant, either alone (81%) or in combination with Devil's Claw (19%). According to subpoenaed documents, these included two products sold by your company under the Soloray brand name (the "Tested Lots"): "Devil's Claw," Lot No. 162208, and "Devil's Claw Special Formula," Lot No. 172706. The products' labels expressly identified the species as "*Harpagophytum procumbens*," *i.e.* as Devil's Claw. The NYBG study concluded that both products instead contained the Substitute Plant.

Because of the implications for consumers, we are contacting your company prior to publication of the NYBG study. This analysis, however, is far from the first to draw attention to serious quality control and compliance problems in the supplement industry. Nor is it the first red flag indicating fraud, misidentification, or other serious problems in the supply chain for Devil's Claw, a popular and scarce plant indigenous to the Kalahari Desert; reports of raw material suppliers mixing or replacing dried Devil's Claw root tubers with the similar-looking dried root tubers of the Substitute Plant—a cheaper plant in the same genus—are common. In this context, the results of the NYBG study are especially troubling; they suggest an industry-wide failure to take necessary steps to comply with law and ensure the accuracy of claims concerning the quality and authenticity of the supplements marketed to consumers.

As a matter of commerce, science, and law, Devil's Claw (*Harpagophytum procumbens*) and the Substitute Plant (*Harpagophytum zeyheri*) are distinct species:

- **Commercially**, Devil's Claw is preferred in virtually all respects, is scarcer, and commands a higher market price. After contacting several suppliers, the Office of the New York Attorney General received price quotes for Devil's Claw root that were *two- to three-times higher* than a similar quote for the Substitute Plant.
- **Scientifically**, the two plants are separate species that can be easily distinguished in the wild. Herbalists link the purported therapeutic properties of Devil's Claw—which are not generally accepted in the medical community or approved by the FDA—to certain naturally-occurring chemical compounds, specifically iridoid glycosides. These chemicals tend to occur naturally in Devil's Claw at much higher concentrations. They also appear in different ratios in the two plants, and at least one chemically potent phenol glycoside in Devil's Claw (6-acetylacteoside) is missing from the Substitute Plant. Moreover, supplements derived from the Substitute Plant—even those "standardized" to deliver a promised percentage of certain iridoid glycosides—are also likely to expose users to other chemicals that are either absent from Devil's Claw or present at lower concentrations.²

² Certain overseas jurisdictions allow the Substitute Plant to be sold as part of the same product as Devil's Claw. This approach has been criticized in the scientific literature due, in part, to the distinct chemical profiles of the two plants and the lack of evidence that the two are pharmacologically equivalent. *See, e.g.,* Nontobeko P. Mncwangi, et al., *What the devil is in your phytomedicine? Exploring species substitution in Harpagophytum through chemometric modeling of ¹H-NMR and UHPLC-MS datasets*, 106 *Phytochemistry* 104-115 (October 2014) ("[O]ur results clearly demonstrate a phytochemical disparity between the two species which may impact on their biological properties. . . . The chemometric analysis results showed that the two species are not chemically equivalent, particularly, that

- Legally, the 1992 Edition of Herbs of Commerce supplies the list of plants that may be sold in the United States commercially under particular common names. 21 C.F.R. 101.4(h).³ The relevant definition—which was reaffirmed in the more recent edition—defines devil’s claw as *Harpagophytum procumbens*, *i.e.* as Devil’s Claw. Representing any plant other than Devil’s Claw as “devil’s claw” is inconsistent with the definition codified in the Herbs of Commerce and is misleading as a matter of law. Misapplying the common name is all the more problematic where, as here, the scientific name of the non-standard species appears nowhere on the label.

Nor are we convinced that the Substitute Plant would be lawful for sale in New York or elsewhere in the United States under its proper scientific name, *i.e.* as *Harpagophytum zeyheri*. Under federal law, a manufacturer may legally sell a “new dietary ingredient”—or an ingredient that was first marketed in the United States after October 15, 1994—if it was (i) used as a source of food; or (ii) submitted to the federal Food and Drug Administration as part of a new dietary ingredient notification at least 75 days prior to initial sale. *See* 21 U.S.C. § 350b; 21 U.S.C. § 331(a); *see also* FDA Draft Guidance on New Dietary Ingredient Notifications, Docket No. FDA-2011-D-0376 76, Fed. Reg. 39111 (July 5, 2011). First, Devil’s Claw has long been marketed in the United States, including as “grapple” and “harpagophytum root.” We have seen no comparable evidence establishing that the Substitute Plant, *i.e.* *Harpagophytum zeyheri*, was sold in the United States prior to 1994, except as an unwanted adulterant.⁴ Second, the Substitute Plant appears to satisfy neither of the requirements for new dietary ingredients.⁵

In connection with an investigation arising under N.Y. Exec. Law § 63(12), N.Y. Gen. Bus. Law § 349, N.Y. Agric. & Mkts. Law § 8, and other authorities, we therefore request a detailed, written response to this letter within 10 business days. In addition to offering you an opportunity to respond to, or dispute any of the analysis above, we ask that your response cover the topics and incorporate the materials identified in the attached Appendix, including but not limited to:

- (i) The methodology and results of any testing your company performs or has performed by a third party on the Tested Lots to independently verify the results of the NYBG study;
- (ii) Your company’s plans for identifying and, where appropriate, recalling any and all non-complying devil’s claw supplements;

harpagoside is not always present in *H. zeyheri*, suggesting that the therapeutic outcome may be different, thus they should not be used interchangeably until pharmacological equivalence has been confirmed.”)

³ Herbs of Commerce seeks to avoid confusion in the herbal supplements marketplace by applying “a single common name in trade . . . to only one botanical name.” *Id.* at I (introduction). The common name “devil’s claw” perfectly illustrates the problem. Overseas and in non-commercial settings, that name has been used loosely to refer to numerous species, including the Substitute Plant as well as other wholly unrelated plants like *Pisonia aculeate*, *Proboscidea altheaefolia*, and *Senegalia greggii*.

⁴ To the contrary, various sources dating back many years identify the Substitute Plant as an unwanted adulterant, which was not legally exported internationally until European standards were loosened in 2003.

⁵ Like many traditional herbal supplements, Devil’s Claw may be administered orally, including as a tea. This does not convert it or the Substitute Plant into a source of food for purposes of the new dietary ingredient requirements.

- (iii) Your company's proposal for identifying and, where appropriate, compensating any defrauded or otherwise harmed consumers; and
- (iv) Any and all new reforms your company will implement to ensure the quality and authenticity of the herbal supplements it manufactures or distributes, including new analytical testing methods.

Notwithstanding this response, we further advise you to preserve and retain any and all documents and communications concerning the subjects addressed in this letter, including but not limited to: (i) the sourcing of ingredients for devil's claw and other herbal dietary supplements; (ii) the measures used to verify the reliability of suppliers of devil's claw and other herbal ingredients; (iii) quality control for devil's claw and other herbal dietary supplements, including awareness of misidentification of herbal products and financially motivated adulteration, with respect to raw materials or finished products; (iv) the labeling and marketing of devil's claw and other herbal supplements; and (v) the manufacturing protocols and testing methods employed to ensure the accuracy of all label and marketing claims relating to the identity, purity, potency, or other characteristics of devil's claw and other herbal supplements.

Please do not hesitate to reach out to our office with any questions or concerns.

Respectfully,



Simon G. Brandler
Senior Advisor & Special Counsel
212-416-6544 / Simon.Brandler@ag.ny.gov

CC John C. Hueston, Hueston Hennigan LLP

APPENDIX

Request for Additional Documentation and Information

With your response, please furnish the following information or documentation:

- (1) For each shipment of ingredients or products your company received since January 1, 2012 that were purportedly derived, in whole or in part, from Devil's Claw and/or the Substitute Plant (the "DC Ingredients"):
 - a. The name, address, telephone number, email address, and other contact information for the supplier from whom your company obtained the shipment;
 - b. The supplier's descriptions of the content of the shipment, as they appeared on order forms, packing slips, contracts, and other written materials;
 - c. The date your company received the shipment;
 - d. The address where your company received the shipment;
 - e. The form in which the DC Ingredients arrived (e.g. powdered extract, cut-and-dried tubers, powdered whole herbs, etc.);
 - f. The address or addresses of the manufacturing facilities that produced any finished supplements containing the DC Ingredients;
 - g. The volume in kilograms of DC Ingredients received;
 - h. The total price your company paid for the DC Ingredients in the shipment in U.S. dollars; and
 - i. Copies of all product labels (front and back) for all supplements produced using the DC Ingredients in that shipment.
- (2) Copies of all audits, reviews, or other documents or communications prepared by your company or a third party to assess the reliability of any supplier who sold DC Ingredients to your company from January 1, 2012 to the present, and a description of any other verification measures not reflected in such documents and communications;
- (3) Copies of all documents and communications, including but not limited to order forms, contracts, packing slips, contracts, correspondence, or other written or electronic materials, concerning the shipment or shipments of DC Ingredients used in manufacturing the Tested Lots;
- (4) A complete description of the methodology and copies of the results of any testing or analyses your company performed or had performed from January 1, 2012 to the present on DC Ingredients or on finished dietary supplements containing DC Ingredients for identity, potency, purity, or any other characteristic, along with a

statement indicating whether any such testing could distinguish between Devil's Claw and the Substitute Plant;

- (5) A complete description of the testing or other measures your company undertook, is undertaking, or intends to undertake to determine the degree to which the products it sold since January 1, 2012 purporting to contain DC Ingredients were adulterated or misbranded, including but not limited to the Tested Lots;
- (6) The results of any and all testing described in response to Item 5 or of any other testing performed on the Tested Lots;
- (7) Copies of any and all documents or communications concerning the Tested Lots or its sale;
- (8) Copies of all documents and communications your company sent to, received from, or exchanged with any employee or agent of the federal Food and Drug Administration ("FDA") since January 1, 2012 concerning inspections of the company facilities identified in response to Item 1(f) above, including but not limited to Form 483s and your company's response thereto.
- (9) For each year from January 1, 2012 to the present, the total annual revenue or, for 2015, the year-to-date revenue your company received respectively from the sale of dietary supplements containing DC Ingredients in (i) retail sales in New York State; (ii) Internet sales to New York State residents; and (iii) the United States overall;
- (10) A proposal for identifying and, as appropriate, compensating any purchasers of devil's claw supplements your company manufactured who may have received adulterated or misbranded products; and
- (11) A complete description of improvements, safeguards, or reforms your company will implement to avoid adulteration or misbranding of herbal dietary supplements in the future, including but not limited to testing or other measures to detect and prevent the adulteration or misbranding of supplement's containing DC Ingredients.



STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

EXECUTIVE DIVISION
SPECIAL COUNSEL

September 9, 2015

David Besins
President and Chief Executive Officer
Olympian Labs, Inc.
21410 N. 15th Lane, Suite 114
Phoenix, Arizona 85027

Re: Misbranding/Adulteration of Devil's Claw Dietary Supplements

Dear Mr. Besins,

This letter constitutes a demand that Olympian Labs, Inc. cease and desist from the marketing, distribution, or sale of misbranded or adulterated devil's claw dietary supplements. For the reasons set forth below, we advise you to furnish the requested documentation and take immediate steps to identify and compensate any consumers who purchased misbranded or adulterated products.

The dietary supplements industry markets devil's claw—the commercial name for the plant *Harpagophytum procumbens* (“Devil's Claw”)—as a purported remedy for arthritis and chronic pain. An independent scientific analysis conducted at the New York Botanical Garden (“NYBG”) concluded that your company sold a devil's claw supplement derived, in whole or in part, from a different, cheaper species that is considered less desirable: *Harpagophytum zeyheri* (the “Substitute Plant”). This would violate several provisions of federal and New York law. *See, e.g.,* 21 U.S.C. §§ 331(a), 342-343; N.Y. Agric. & Mkts. Law § 199-a; N.Y. Gen. Bus. Law § 349.

Scientists affiliated with NYBG, a leading botanical research center, used a DNA barcoding technique to identify the relevant plant source for a range of supplements labeled as containing devil's claw or devil's claw extract.¹ The NYBG study revealed widespread

¹ DNA barcoding is a sophisticated genetic technique that relies on short, unique sequences of DNA to identify the source of plant or animal material. To carry out the NYBG study, researchers first identified unique mini-barcodes, specifically focused on the *psbAtrnH* genetic marker, to distinguish between the two *Harpagophytum* species. The study analyzed 23 supplements labeled as containing devil's claw or a devil's claw extract, including both single-ingredient supplements and complex mixtures. Five of the tested supplements were produced by non-U.S. companies and labeled for overseas sale, and are therefore excluded from the results discussed in this letter. Of the 18 supplements labeled for sale in the United States, NYBG extracted identifiable DNA from all but two of the products. (Only one of the two is labeled as an “extract” in the “supplement facts” panel.)

substitution and adulteration; of 16 U.S. made devil's claw supplements where the relevant plant source could be identified—produced by 14 separate companies, including large and small firms—**100%** were found to contain the Substitute Plant, either alone (81%) or in combination with Devil's Claw (19%). According to subpoenaed documents, this included a product sold by your company under the name "Prescribed Choice Joint Defense Plus," Lot No. 12291A (the "Tested Lot"). Your product's label expressly identified the species as "*Harpagophytum procumbens*," i.e. as Devil's Claw. The NYBG study concluded that your company's product instead contained the Substitute Plant.

Because of the implications for consumers, we are contacting your company prior to publication of the NYBG study. This analysis, however, is far from the first to draw attention to serious quality control and compliance problems in the supplement industry. Nor is it the first red flag indicating fraud, misidentification, or other serious problems in the supply chain for Devil's Claw, a popular and scarce plant indigenous to the Kalahari Desert; reports of raw material suppliers mixing or replacing dried Devil's Claw root tubers with the similar-looking dried root tubers of the Substitute Plant—a cheaper plant in the same genus—are common. In this context, the results of the NYBG study are especially troubling; they suggest an industry-wide failure to take necessary steps to comply with law and ensure the accuracy of claims concerning the quality and authenticity of the supplements marketed to consumers.

As a matter of commerce, science, and law, Devil's Claw (*Harpagophytum procumbens*) and the Substitute Plant (*Harpagophytum zeyheri*) are distinct species:

- **Commercially**, Devil's Claw is preferred in virtually all respects, is scarcer, and commands a higher market price. After contacting several suppliers, the Office of the New York Attorney General received price quotes for Devil's Claw root that were *two- to three-times higher* than a similar quote for the Substitute Plant.
- **Scientifically**, the two plants are separate species that can be easily distinguished in the wild. Herbalists link the purported therapeutic properties of Devil's Claw—which are not generally accepted in the medical community or approved by the FDA—to certain naturally-occurring chemical compounds, specifically iridoid glycosides. These chemicals tend to occur naturally in Devil's Claw at much higher concentrations. They also appear in different ratios in the two plants, and at least one chemically potent phenol glycoside in Devil's Claw (6-acetylacteoside) is missing from the Substitute Plant. Moreover, supplements derived from the Substitute Plant—even those "standardized" to deliver a promised percentage of certain iridoid glycosides—are also likely to expose users to other chemicals that are either absent from Devil's Claw or present at lower concentrations.²

² Certain overseas jurisdictions allow the Substitute Plant to be sold as part of the same product as Devil's Claw. This approach has been criticized in the scientific literature due, in part, to the distinct chemical profiles of the two plants and the lack of evidence that the two are pharmacologically equivalent. See, e.g., Nontobeko P. Mncwangi, et al., *What the devil is in your phytomedicine? Exploring species substitution in Harpagophytum through chemometric modeling of ¹H-NMR and UHPLC-MS datasets*, 106 *Phytochemistry* 104-115 (October 2014) ("[O]ur results clearly demonstrate a phytochemical disparity between the two species which may impact on their biological properties. . . . The chemometric analysis results showed that the two species are not chemically equivalent, particularly, that

- Legally, the 1992 Edition of Herbs of Commerce supplies the list of plants that may be sold in the United States commercially under particular common names. 21 C.F.R. 101.4(h).³ The relevant definition—which was reaffirmed in the more recent edition—defines devil’s claw as *Harpagophytum procumbens*, *i.e.* as Devil’s Claw. Representing any plant other than Devil’s Claw as “devil’s claw” is inconsistent with the definition codified in the Herbs of Commerce and is misleading as a matter of law. Misapplying the common name is all the more problematic where, as here, the scientific name of the non-standard species appears nowhere on the label.

Nor are we convinced that the Substitute Plant would be lawful for sale in New York or elsewhere in the United States under its proper scientific name, *i.e.* as *Harpagophytum zeyheri*. Under federal law, a manufacturer may legally sell a “new dietary ingredient”—or an ingredient that was first marketed in the United States after October 15, 1994—if it was (i) used as a source of food; or (ii) submitted to the federal Food and Drug Administration as part of a new dietary ingredient notification at least 75 days prior to initial sale. *See* 21 U.S.C. § 350b; 21 U.S.C. § 331(a); *see also* FDA Draft Guidance on New Dietary Ingredient Notifications, Docket No. FDA-2011-D-0376 76, Fed. Reg. 39111 (July 5, 2011). First, Devil’s Claw has long been marketed in the United States, including as “grapple” and “harpagophytum root.” We have seen no comparable evidence establishing that the Substitute Plant, *i.e.* *Harpagophytum zeyheri*, was sold in the United States prior to 1994, except as an unwanted adulterant.⁴ Second, the Substitute Plant appears to satisfy neither of the requirements for new dietary ingredients.⁵

In connection with an investigation arising under N.Y. Exec. Law § 63(12), N.Y. Gen. Bus. Law § 349, N.Y. Agric. & Mkts. Law § 8, and other authorities, we therefore request a detailed, written response to this letter within 10 business days. In addition to offering you an opportunity to respond to, or dispute any of the analysis above, we ask that your response cover the topics and incorporate the materials identified in the attached Appendix, including but not limited to:

- (i) The methodology and results of any testing your company performs or has performed by a third party on the Tested Lot to independently verify the results of the NYBG study;
- (ii) Your company’s plans for identifying and, where appropriate, recalling any and all non-complying devil’s claw supplements;

harpagoside is not always present in *H. zeyheri*, suggesting that the therapeutic outcome may be different, thus they should not be used interchangeably until pharmacological equivalence has been confirmed.”)

³ Herbs of Commerce seeks to avoid confusion in the herbal supplements marketplace by applying “a single common name in trade . . . to only one botanical name.” *Id.* at I (introduction). The common name “devil’s claw” perfectly illustrates the problem. Overseas and in non-commercial settings, that name has been used loosely to refer to numerous species, including the Substitute Plant as well as other wholly unrelated plants like *Pisonia aculeate*, *Proboscidea altheaefolia*, and *Senegalia greggii*.

⁴ To the contrary, various sources dating back many years identify the Substitute Plant as an unwanted adulterant, which was not legally exported internationally until European standards were loosened in 2003.

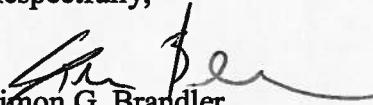
⁵ Like many traditional herbal supplements, Devil’s Claw may be administered orally, including as a tea. This does not convert it or the Substitute Plant into a source of food for purposes of the new dietary ingredient requirements.

- (iii) Your company's proposal for identifying and, where appropriate, compensating any defrauded or otherwise harmed consumers; and
- (iv) Any and all new reforms your company will implement to ensure the quality and authenticity of the herbal supplements it manufactures or distributes, including new analytical testing methods.

Notwithstanding this response, we further advise you to preserve and retain any and all documents and communications concerning the subjects addressed in this letter, including but not limited to: (i) the sourcing of ingredients for devil's claw and other herbal dietary supplements; (ii) the measures used to verify the reliability of suppliers of devil's claw and other herbal ingredients; (iii) quality control for devil's claw and other herbal dietary supplements, including awareness of misidentification of herbal products and financially motivated adulteration, with respect to raw materials or finished products; (iv) the labeling and marketing of devil's claw and other herbal supplements; and (v) the manufacturing protocols and testing methods employed to ensure the accuracy of all label and marketing claims relating to the identity, purity, potency, or other characteristics of devil's claw and other herbal supplements.

Please do not hesitate to reach out to our office with any questions or concerns.

Respectfully,


Simon G. Brandler
Senior Advisor & Special Counsel
212-416-6544 / Simon.Brandler@ag.ny.gov

APPENDIX

Request for Additional Documentation and Information

With your response, please furnish the following information or documentation:

- (1) For each shipment of ingredients or products your company received since January 1, 2012 that were purportedly derived, in whole or in part, from Devil's Claw and/or the Substitute Plant (the "DC Ingredients"):
 - a. The name, address, telephone number, email address, and other contact information for the supplier from whom your company obtained the shipment;
 - b. The supplier's descriptions of the content of the shipment, as they appeared on order forms, packing slips, contracts, and other written materials;
 - c. The date your company received the shipment;
 - d. The address where your company received the shipment;
 - e. The form in which the DC Ingredients arrived (e.g. powdered extract, cut-and-dried tubers, powdered whole herbs, etc.);
 - f. The address or addresses of the manufacturing facilities that produced any finished supplements containing the DC Ingredients;
 - g. The volume in kilograms of DC Ingredients received;
 - h. The total price your company paid for the DC Ingredients in the shipment in U.S. dollars; and
 - i. Copies of all product labels (front and back) for all supplements produced using the DC Ingredients in that shipment.
- (2) Copies of all audits, reviews, or other documents or communications prepared by your company or a third party to assess the reliability of any supplier who sold DC Ingredients to your company from January 1, 2012 to the present, and a description of any other verification measures not reflected in such documents and communications;
- (3) Copies of all documents and communications, including but not limited to order forms, contracts, packing slips, contracts, correspondence, or other written or electronic materials, concerning the shipment or shipments of DC Ingredients used in manufacturing the Tested Lot;
- (4) A complete description of the methodology and copies of the results of any testing or analyses your company performed or had performed from January 1, 2012 to the present on DC Ingredients or on finished dietary supplements containing DC Ingredients for identity, potency, purity, or any other characteristic, along with a

statement indicating whether any such testing could distinguish between Devil's Claw and the Substitute Plant;

- (5) A complete description of the testing or other measures your company undertook, is undertaking, or intends to undertake to determine the degree to which the products it sold since January 1, 2012 purporting to contain DC Ingredients were adulterated or misbranded, including but not limited to the Tested Lot;
- (6) The results of any and all testing described in response to Item 5 or of any other testing performed on the Tested Lot;
- (7) Copies of any and all documents or communications concerning the Tested Lot or its sale;
- (8) Copies of all documents and communications your company sent to, received from, or exchanged with any employee or agent of the federal Food and Drug Administration ("FDA") since January 1, 2012 concerning inspections of the company facilities identified in response to Item 1(f) above, including but not limited to Form 483s and your company's response thereto.
- (9) For each year from January 1, 2012 to the present, the total annual revenue or, for 2015, the year-to-date revenue your company received respectively from the sale of dietary supplements containing DC Ingredients in (i) retail sales in New York State; (ii) Internet sales to New York State residents; and (iii) the United States overall;
- (10) A proposal for identifying and, as appropriate, compensating any purchasers of devil's claw supplements your company manufactured who may have received adulterated or misbranded products; and
- (11) A complete description of improvements, safeguards, or reforms your company will implement to avoid adulteration or misbranding of herbal dietary supplements in the future, including but not limited to testing or other measures to detect and prevent the adulteration or misbranding of supplement's containing DC Ingredients.



STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

EXECUTIVE DIVISION
SPECIAL COUNSEL

September 9, 2015

Thomas J. Petrarca
President and CEO
RHG & Company Inc. d/b/a Vital Nutrients
45 Kenneth Dooley Drive
Middletown, CT 06457

Re: Misbranding/Adulteration of Devil's Claw Dietary Supplements

Dear Mr. Petrarca,

This letter constitutes a demand that RHG & Company Inc. d/b/a Vital Nutrients cease and desist from the marketing, distribution, or sale of misbranded or adulterated devil's claw dietary supplements. For the reasons set forth below, we advise you to furnish the requested documentation and take immediate steps to identify and compensate any consumers who purchased misbranded or adulterated products.

The dietary supplements industry markets devil's claw—the commercial name for the plant *Harpagophytum procumbens* (“Devil's Claw”)—as a purported remedy for arthritis and chronic pain. An independent scientific analysis conducted at the New York Botanical Garden (“NYBG”) concluded that your company sold a devil's claw supplement derived, in whole or in part, from a different, cheaper species that is considered less desirable: *Harpagophytum zeyheri* (the “Substitute Plant”). This would violate several provisions of federal and New York law. *See, e.g.*, 21 U.S.C. §§ 331(a), 342-343; N.Y. Agric. & Mkts. Law § 199-a; N.Y. Gen. Bus. Law § 349.

Scientists affiliated with NYBG, a leading botanical research center, used a DNA barcoding technique to identify the relevant plant source for a range of supplements labeled as containing devil's claw or devil's claw extract.¹ The NYBG study revealed widespread

¹ DNA barcoding is a sophisticated genetic technique that relies on short, unique sequences of DNA to identify the source of plant or animal material. To carry out the NYBG study, researchers first identified unique mini-barcodes, specifically focused on the *psbAtrnH* genetic marker, to distinguish between the two *Harpagophytum* species. The study analyzed 23 supplements labeled as containing devil's claw or a devil's claw extract, including both single-ingredient supplements and complex mixtures. Five of the tested supplements were produced by non-U.S. companies and labeled for overseas sale, and are therefore excluded from the results discussed in this letter. Of the 18 supplements labeled for sale in the United States, NYBG extracted identifiable DNA from all but two of the products. (Only one of the two is labeled as an “extract” in the “supplement facts” panel.)

substitution and adulteration; of 16 U.S. made devil's claw supplements where the relevant plant source could be identified—produced by 14 separate companies, including large and small firms—**100%** were found to contain the Substitute Plant, either alone (81%) or in combination with Devil's Claw (19%). According to subpoenaed documents, this included a product sold by your company under the name "Vital Nutrients Joint Ease," Lot No. 13E40 (the "Tested Lot"). Your product's label expressly identified the species as "*Harpagophytum procumbens*," *i.e.* as Devil's Claw. The NYBG study concluded that your company's product instead contained the Substitute Plant.

Because of the implications for consumers, we are contacting your company prior to publication of the NYBG study. This analysis, however, is far from the first to draw attention to serious quality control and compliance problems in the supplement industry. Nor is it the first red flag indicating fraud, misidentification, or other serious problems in the supply chain for Devil's Claw, a popular and scarce plant indigenous to the Kalahari Desert; reports of raw material suppliers mixing or replacing dried Devil's Claw root tubers with the similar-looking dried root tubers of the Substitute Plant—a cheaper plant in the same genus—are common. In this context, the results of the NYBG study are especially troubling; they suggest an industry-wide failure to take necessary steps to comply with law and ensure the accuracy of claims concerning the quality and authenticity of the supplements marketed to consumers.

As a matter of commerce, science, and law, Devil's Claw (*Harpagophytum procumbens*) and the Substitute Plant (*Harpagophytum zeyheri*) are distinct species:

- **Commercially**, Devil's Claw is preferred in virtually all respects, is scarcer, and commands a higher market price. After contacting several suppliers, the Office of the New York Attorney General received price quotes for Devil's Claw root that were *two- to three-times higher* than a similar quote for the Substitute Plant.
- **Scientifically**, the two plants are separate species that can be easily distinguished in the wild. Herbalists link the purported therapeutic properties of Devil's Claw—which are not generally accepted in the medical community or approved by the FDA—to certain naturally-occurring chemical compounds, specifically iridoid glycosides. These chemicals tend to occur naturally in Devil's Claw at much higher concentrations. They also appear in different ratios in the two plants, and at least one chemically potent phenol glycoside in Devil's Claw (6-acetylacteoside) is missing from the Substitute Plant. Moreover, supplements derived from the Substitute Plant—even those "standardized" to deliver a promised percentage of certain iridoid glycosides—are also likely to expose users to other chemicals that are either absent from Devil's Claw or present at lower concentrations.²

² Certain overseas jurisdictions allow the Substitute Plant to be sold as part of the same product as Devil's Claw. This approach has been criticized in the scientific literature due, in part, to the distinct chemical profiles of the two plants and the lack of evidence that the two are pharmacologically equivalent. *See, e.g.,* Nontobeko P. Mncwangi, et al., *What the devil is in your phytoedicine? Exploring species substitution in Harpagophytum through chemometric modeling of ¹H-NMR and UHPLC-MS datasets*, 106 *Phytochemistry* 104-115 (October 2014) ("[O]ur results clearly demonstrate a phytochemical disparity between the two species which may impact on their biological properties. . . . The chemometric analysis results showed that the two species are not chemically equivalent, particularly, that

- Legally, the 1992 Edition of Herbs of Commerce supplies the list of plants that may be sold in the United States commercially under particular common names. 21 C.F.R. 101.4(h).³ The relevant definition—which was reaffirmed in the more recent edition—defines devil’s claw as *Harpagophytum procumbens*, *i.e.* as Devil’s Claw. Representing any plant other than Devil’s Claw as “devil’s claw” is inconsistent with the definition codified in the Herbs of Commerce and is misleading as a matter of law. Misapplying the common name is all the more problematic where, as here, the scientific name of the non-standard species appears nowhere on the label.

Nor are we convinced that the Substitute Plant would be lawful for sale in New York or elsewhere in the United States under its proper scientific name, *i.e.* as *Harpagophytum zeyheri*. Under federal law, a manufacturer may legally sell a “new dietary ingredient”—or an ingredient that was first marketed in the United States after October 15, 1994—if it was (i) used as a source of food; or (ii) submitted to the federal Food and Drug Administration as part of a new dietary ingredient notification at least 75 days prior to initial sale. *See* 21 U.S.C. § 350b; 21 U.S.C. § 331(a); *see also* FDA Draft Guidance on New Dietary Ingredient Notifications, Docket No. FDA-2011-D-0376 76, Fed. Reg. 39111 (July 5, 2011). First, Devil’s Claw has long been marketed in the United States, including as “grapple” and “harpagophytum root.” We have seen no comparable evidence establishing that the Substitute Plant, *i.e.* *Harpagophytum zeyheri*, was sold in the United States prior to 1994, except as an unwanted adulterant.⁴ Second, the Substitute Plant appears to satisfy neither of the requirements for new dietary ingredients.⁵

In connection with an investigation arising under N.Y. Exec. Law § 63(12), N.Y. Gen. Bus. Law § 349, N.Y. Agric. & Mkts. Law § 8, and other authorities, we therefore request a detailed, written response to this letter within 10 business days. In addition to offering you an opportunity to respond to, or dispute any of the analysis above, we ask that your response cover the topics and incorporate the materials identified in the attached Appendix, including but not limited to:

- (i) The methodology and results of any testing your company performs or has performed by a third party on the Tested Lot to independently verify the results of the NYBG study;
- (ii) Your company’s plans for identifying and, where appropriate, recalling any and all non-complying devil’s claw supplements;

harpagoside is not always present in *H. zeyheri*, suggesting that the therapeutic outcome may be different, thus they should not be used interchangeably until pharmacological equivalence has been confirmed.”)

³ Herbs of Commerce seeks to avoid confusion in the herbal supplements marketplace by applying “a single common name in trade . . . to only one botanical name.” *Id.* at I (introduction). The common name “devil’s claw” perfectly illustrates the problem. Overseas and in non-commercial settings, that name has been used loosely to refer to numerous species, including the Substitute Plant as well as other wholly unrelated plants like *Pisonia aculeate*, *Proboscidea altheaefolia*, and *Senegalia greggii*.

⁴ To the contrary, various sources dating back many years identify the Substitute Plant as an unwanted adulterant, which was not legally exported internationally until European standards were loosened in 2003.

⁵ Like many traditional herbal supplements, Devil’s Claw may be administered orally, including as a tea. This does not convert it or the Substitute Plant into a source of food for purposes of the new dietary ingredient requirements.

- (iii) Your company's proposal for identifying and, where appropriate, compensating any defrauded or otherwise harmed consumers; and
- (iv) Any and all new reforms your company will implement to ensure the quality and authenticity of the herbal supplements it manufactures or distributes, including new analytical testing methods.

Notwithstanding this response, we further advise you to preserve and retain any and all documents and communications concerning the subjects addressed in this letter, including but not limited to: (i) the sourcing of ingredients for devil's claw and other herbal dietary supplements; (ii) the measures used to verify the reliability of suppliers of devil's claw and other herbal ingredients; (iii) quality control for devil's claw and other herbal dietary supplements, including awareness of misidentification of herbal products and financially motivated adulteration, with respect to raw materials or finished products; (iv) the labeling and marketing of devil's claw and other herbal supplements; and (v) the manufacturing protocols and testing methods employed to ensure the accuracy of all label and marketing claims relating to the identity, purity, potency, or other characteristics of devil's claw and other herbal supplements.

Please do not hesitate to reach out to our office with any questions or concerns.

Respectfully,



Simon G. Brandler
Senior Advisor & Special Counsel
212-416-6544 / Simon.Brandler@ag.ny.gov

APPENDIX

Request for Additional Documentation and Information

With your response, please furnish the following information or documentation:

- (1) For each shipment of ingredients or products your company received since January 1, 2012 that were purportedly derived, in whole or in part, from Devil's Claw and/or the Substitute Plant (the "DC Ingredients"):
 - a. The name, address, telephone number, email address, and other contact information for the supplier from whom your company obtained the shipment;
 - b. The supplier's descriptions of the content of the shipment, as they appeared on order forms, packing slips, contracts, and other written materials;
 - c. The date your company received the shipment;
 - d. The address where your company received the shipment;
 - e. The form in which the DC Ingredients arrived (e.g. powdered extract, cut-and-dried tubers, powdered whole herbs, etc.);
 - f. The address or addresses of the manufacturing facilities that produced any finished supplements containing the DC Ingredients;
 - g. The volume in kilograms of DC Ingredients received;
 - h. The total price your company paid for the DC Ingredients in the shipment in U.S. dollars; and
 - i. Copies of all product labels (front and back) for all supplements produced using the DC Ingredients in that shipment.
- (2) Copies of all audits, reviews, or other documents or communications prepared by your company or a third party to assess the reliability of any supplier who sold DC Ingredients to your company from January 1, 2012 to the present, and a description of any other verification measures not reflected in such documents and communications;
- (3) Copies of all documents and communications, including but not limited to order forms, contracts, packing slips, contracts, correspondence, or other written or electronic materials, concerning the shipment or shipments of DC Ingredients used in manufacturing the Tested Lot;
- (4) A complete description of the methodology and copies of the results of any testing or analyses your company performed or had performed from January 1, 2012 to the present on DC Ingredients or on finished dietary supplements containing DC Ingredients for identity, potency, purity, or any other characteristic, along with a

statement indicating whether any such testing could distinguish between Devil's Claw and the Substitute Plant;

- (5) A complete description of the testing or other measures your company undertook, is undertaking, or intends to undertake to determine the degree to which the products it sold since January 1, 2012 purporting to contain DC Ingredients were adulterated or misbranded, including but not limited to the Tested Lot;
- (6) The results of any and all testing described in response to Item 5 or of any other testing performed on the Tested Lot;
- (7) Copies of any and all documents or communications concerning the Tested Lot or its sale;
- (8) Copies of all documents and communications your company sent to, received from, or exchanged with any employee or agent of the federal Food and Drug Administration ("FDA") since January 1, 2012 concerning inspections of the company facilities identified in response to Item 1(f) above, including but not limited to Form 483s and your company's response thereto.
- (9) For each year from January 1, 2012 to the present, the total annual revenue or, for 2015, the year-to-date revenue your company received respectively from the sale of dietary supplements containing DC Ingredients in (i) retail sales in New York State; (ii) Internet sales to New York State residents; and (iii) the United States overall;
- (10) A proposal for identifying and, as appropriate, compensating any purchasers of devil's claw supplements your company manufactured who may have received adulterated or misbranded products; and
- (11) A complete description of improvements, safeguards, or reforms your company will implement to avoid adulteration or misbranding of herbal dietary supplements in the future, including but not limited to testing or other measures to detect and prevent the adulteration or misbranding of supplement's containing DC Ingredients.



STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

EXECUTIVE DIVISION
SPECIAL COUNSEL

September 9, 2015

Paul Jacobson
Chief Executive Officer
Thorne Research Inc.
P.O. Box 25
Dover, Idaho, 83825

Re: Misbranding/Adulteration of Devil's Claw Dietary Supplements

Dear Mr. Jacobson,

This letter constitutes a demand that Thorne Research, Inc. cease and desist from the marketing, distribution, or sale of misbranded or adulterated devil's claw dietary supplements. For the reasons set forth below, we advise you to furnish the requested documentation and take immediate steps to identify and compensate any consumers who purchased misbranded or adulterated products.

The dietary supplements industry markets devil's claw—the commercial name for the plant *Harpagophytum procumbens* (“Devil's Claw”)—as a purported remedy for arthritis and chronic pain. An independent scientific analysis conducted at the New York Botanical Garden (“NYBG”) concluded that your company sold a devil's claw supplement derived, in whole or in part, from a different, cheaper species that is considered less desirable: *Harpagophytum zeyheri* (the “Substitute Plant”). This would violate several provisions of federal and New York law. *See, e.g.,* 21 U.S.C. §§ 331(a), 342-343; N.Y. Agric. & Mkts. Law § 199-a; N.Y. Gen. Bus. Law § 349.

Scientists affiliated with NYBG, a leading botanical research center, used a DNA barcoding technique to identify the relevant plant source for a range of supplements labeled as containing devil's claw or devil's claw extract.¹ The NYBG study revealed widespread

¹ DNA barcoding is a sophisticated genetic technique that relies on short, unique sequences of DNA to identify the source of plant or animal material. To carry out the NYBG study, researchers first identified unique mini-barcodes, specifically focused on the *psbAtrnH* genetic marker, to distinguish between the two *Harpagophytum* species. The study analyzed 23 supplements labeled as containing devil's claw or a devil's claw extract, including both single-ingredient supplements and complex mixtures. Five of the tested supplements were produced by non-U.S. companies and labeled for overseas sale, and are therefore excluded from the results discussed in this letter. Of the 18 supplements labeled for sale in the United States, NYBG extracted identifiable DNA from all but two of the products. (Only one of the two is labeled as an “extract” in the “supplement facts” panel.)

substitution and adulteration; of 16 U.S.-made devil's claw supplements where the relevant plant source could be identified—produced by 14 separate companies, including large and small firms—**100%** were found to contain the Substitute Plant, either alone (81%) or in combination with Devil's Claw (19%). According to subpoenaed documents, this included a product sold by your company under the name "AR-ENCAP," Lot No. 309193 (the "Tested Lot"). Your product's label expressly identified the relevant species as "*Harpagophytum procumbens*," i.e. as Devil's Claw. The NYBG study concluded that your company's product instead contained the Substitute Plant.

Because of the implications for consumers, we are contacting your company prior to publication of the NYBG study. This analysis, however, is far from the first to draw attention to serious quality control and compliance problems in the supplement industry. Nor is it the first red flag indicating fraud, misidentification, or other serious problems in the supply chain for Devil's Claw, a popular and scarce plant indigenous to the Kalahari Desert; reports of raw material suppliers mixing or replacing dried Devil's Claw root tubers with the similar-looking dried root tubers of the Substitute Plant—a cheaper plant in the same genus—are common. In this context, the results of the NYBG study are especially troubling; they suggest an industry-wide failure to take necessary steps to comply with law and ensure the accuracy of claims concerning the quality and authenticity of the supplements marketed to consumers.

As a matter of commerce, science, and law, Devil's Claw (*Harpagophytum procumbens*) and the Substitute Plant (*Harpagophytum zeyheri*) are distinct species:

- **Commercially**, Devil's Claw is preferred in virtually all respects, is scarcer, and commands a higher market price. After contacting several suppliers, the Office of the New York Attorney General received price quotes for Devil's Claw root that were *two- to three-times higher* than a similar quote for the Substitute Plant.
- **Scientifically**, the two plants are separate species that can be easily distinguished in the wild. Herbalists link the purported therapeutic properties of Devil's Claw—which are not generally accepted in the medical community or approved by the FDA—to certain naturally-occurring chemical compounds, specifically iridoid glycosides. These chemicals tend to occur naturally in Devil's Claw at much higher concentrations. They also appear in different ratios in the two plants, and at least one chemically potent phenol glycoside in Devil's Claw (6-acetylacteoside) is missing from the Substitute Plant. Moreover, supplements derived from the Substitute Plant—even those "standardized" to deliver a promised percentage of certain iridoid glycosides—are also likely to expose users to other chemicals that are either absent from Devil's Claw or present at lower concentrations.²

² Certain overseas jurisdictions allow the Substitute Plant to be sold as part of the same product as Devil's Claw. This approach has been criticized in the scientific literature due, in part, to the distinct chemical profiles of the two plants and the lack of evidence that the two are pharmacologically equivalent. See, e.g., Nontobeko P. Mncwangi, et al., *What the devil is in your phytomedicine? Exploring species substitution in Harpagophytum through chemometric modeling of ¹H-NMR and UHPLC-MS datasets*, 106 *Phytochemistry* 104-115 (October 2014) ("[O]ur results clearly demonstrate a phytochemical disparity between the two species which may impact on their biological properties. . . . The chemometric analysis results showed that the two species are not chemically equivalent, particularly, that

- Legally, the 1992 Edition of Herbs of Commerce supplies the list of plants that may be sold in the United States commercially under particular common names. 21 C.F.R. 101.4(h).³ The relevant definition—which was reaffirmed in the more recent edition—defines devil’s claw as *Harpagophytum procumbens*, *i.e.* as Devil’s Claw. Representing any plant other than Devil’s Claw as “devil’s claw” is inconsistent with the definition codified in the Herbs of Commerce and is misleading as a matter of law. Misapplying the common name is all the more problematic where, as here, the scientific name of the non-standard species appears nowhere on the label.

Nor are we convinced that the Substitute Plant would be lawful for sale in New York or elsewhere in the United States under its proper scientific name, *i.e.* as *Harpagophytum zeyheri*. Under federal law, a manufacturer may legally sell a “new dietary ingredient”—or an ingredient that was first marketed in the United States after October 15, 1994—if it was (i) used as a source of food; or (ii) submitted to the federal Food and Drug Administration as part of a new dietary ingredient notification at least 75 days prior to initial sale. *See* 21 U.S.C. § 350b; 21 U.S.C. § 331(a); *see also* FDA Draft Guidance on New Dietary Ingredient Notifications, Docket No. FDA-2011-D-0376 76, Fed. Reg. 39111 (July 5, 2011). First, Devil’s Claw has long been marketed in the United States, including as “grapple” and “harpagophytum root.” We have seen no comparable evidence establishing that the Substitute Plant, *i.e.* *Harpagophytum zeyheri*, was sold in the United States prior to 1994, except as an unwanted adulterant.⁴ Second, the Substitute Plant appears to satisfy neither of the requirements for new dietary ingredients.⁵

In connection with an investigation arising under N.Y. Exec. Law § 63(12), N.Y. Gen. Bus. Law § 349, N.Y. Agric. & Mkts. Law § 8, and other authorities, we therefore request a detailed, written response to this letter within 10 business days. In addition to offering you an opportunity to respond to, or dispute any of the analysis above, we ask that your response cover the topics and incorporate the materials identified in the attached Appendix, including but not limited to:

- (i) The methodology and results of any testing your company performs or has performed by a third party on the Tested Lot to independently verify the results of the NYBG study;
- (ii) Your company’s plans for identifying and, where appropriate, recalling any and all non-complying devil’s claw supplements;

harpagoside is not always present in *H. zeyheri*, suggesting that the therapeutic outcome may be different, thus they should not be used interchangeably until pharmacological equivalence has been confirmed.”)

³ Herbs of Commerce seeks to avoid confusion in the herbal supplements marketplace by applying “a single common name in trade . . . to only one botanical name.” *Id.* at I (introduction). The common name “devil’s claw” perfectly illustrates the problem. Overseas and in non-commercial settings, that name has been used loosely to refer to numerous species, including the Substitute Plant as well as other wholly unrelated plants like *Pisonia aculeate*, *Proboscidea altheaefolia*, and *Senegalia greggii*.

⁴ To the contrary, various sources dating back many years identify the Substitute Plant as an unwanted adulterant, which was not legally exported internationally until European standards were loosened in 2003.

⁵ Like many traditional herbal supplements, Devil’s Claw may be administered orally, including as a tea. This does not convert it or the Substitute Plant into a source of food for purposes of the new dietary ingredient requirements.

- (iii) Your company's proposal for identifying and, where appropriate, compensating any defrauded or otherwise harmed consumers; and
- (iv) Any and all new reforms your company will implement to ensure the quality and authenticity of the herbal supplements it manufactures or distributes, including new analytical testing methods.

Notwithstanding this response, we further advise you to preserve and retain any and all documents and communications concerning the subjects addressed in this letter, including but not limited to: (i) the sourcing of ingredients for devil's claw and other herbal dietary supplements; (ii) the measures used to verify the reliability of suppliers of devil's claw and other herbal ingredients; (iii) quality control for devil's claw and other herbal dietary supplements, including awareness of misidentification of herbal products and financially motivated adulteration, with respect to raw materials or finished products; (iv) the labeling and marketing of devil's claw and other herbal supplements; and (v) the manufacturing protocols and testing methods employed to ensure the accuracy of all label and marketing claims relating to the identity, purity, potency, or other characteristics of devil's claw and other herbal supplements.

Please do not hesitate to reach out to our office with any questions or concerns.

Respectfully,



Simon G. Brandler
Senior Advisor & Special Counsel
212-416-6544 / Simon.Brandler@ag.ny.gov

APPENDIX

Request for Additional Documentation and Information

With your response, please furnish the following information or documentation:

- (1) For each shipment of ingredients or products your company received since January 1, 2012 that were purportedly derived, in whole or in part, from Devil's Claw and/or the Substitute Plant (the "DC Ingredients"):
 - a. The name, address, telephone number, email address, and other contact information for the supplier from whom your company obtained the shipment;
 - b. The supplier's descriptions of the content of the shipment, as they appeared on order forms, packing slips, contracts, and other written materials;
 - c. The date your company received the shipment;
 - d. The address where your company received the shipment;
 - e. The form in which the DC Ingredients arrived (e.g. powdered extract, cut-and-dried tubers, powdered whole herbs, etc.);
 - f. The address or addresses of the manufacturing facilities that produced any finished supplements containing the DC Ingredients;
 - g. The volume in kilograms of DC Ingredients received;
 - h. The total price your company paid for the DC Ingredients in the shipment in U.S. dollars; and
 - i. Copies of all product labels (front and back) for all supplements produced using the DC Ingredients in that shipment.
- (2) Copies of all audits, reviews, or other documents or communications prepared by your company or a third party to assess the reliability of any supplier who sold DC Ingredients to your company from January 1, 2012 to the present, and a description of any other verification measures not reflected in such documents and communications;
- (3) Copies of all documents and communications, including but not limited to order forms, contracts, packing slips, contracts, correspondence, or other written or electronic materials, concerning the shipment or shipments of DC Ingredients used in manufacturing the Tested Lot;
- (4) A complete description of the methodology and copies of the results of any testing or analyses your company performed or had performed from January 1, 2012 to the present on DC Ingredients or on finished dietary supplements containing DC Ingredients for identity, potency, purity, or any other characteristic, along with a

statement indicating whether any such testing could distinguish between Devil's Claw and the Substitute Plant;

- (5) A complete description of the testing or other measures your company undertook, is undertaking, or intends to undertake to determine the degree to which the products it sold since January 1, 2012 purporting to contain DC Ingredients were adulterated or misbranded, including but not limited to the Tested Lot;
- (6) The results of any and all testing described in response to Item 5 or of any other testing performed on the Tested Lot;
- (7) Copies of any and all documents or communications concerning the Tested Lot or its sale;
- (8) Copies of all documents and communications your company sent to, received from, or exchanged with any employee or agent of the federal Food and Drug Administration ("FDA") since January 1, 2012 concerning inspections of the company facilities identified in response to Item 1(f) above, including but not limited to Form 483s and your company's response thereto.
- (9) For each year from January 1, 2012 to the present, the total annual revenue or, for 2015, the year-to-date revenue your company received respectively from the sale of dietary supplements containing DC Ingredients in (i) retail sales in New York State; (ii) Internet sales to New York State residents; and (iii) the United States overall;
- (10) A proposal for identifying and, as appropriate, compensating any purchasers of devil's claw supplements your company manufactured who may have received adulterated or misbranded products; and
- (11) A complete description of improvements, safeguards, or reforms your company will implement to avoid adulteration or misbranding of herbal dietary supplements in the future, including but not limited to testing or other measures to detect and prevent the adulteration or misbranding of supplement's containing DC Ingredients.



STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

EXECUTIVE DIVISION
SPECIAL COUNSEL

September 9, 2015

Hazel M. Correll
TUDUVZ, LLC
937 S. 250 W.
Peru, Indiana 46970

Re: Misbranding/Adulteration of Devil's Claw Dietary Supplements

Dear Ms. Correll,

This letter constitutes a demand that TUDUVZ d/b/a The Natural Healing Room & End Time Essentials cease and desist from the marketing, distribution, or sale of misbranded or adulterated devil's claw dietary supplements. For the reasons set forth below, we advise you to furnish the requested documentation and take immediate steps to identify and compensate any consumers who purchased misbranded or adulterated products.

The dietary supplements industry markets devil's claw—the commercial name for the plant *Harpagophytum procumbens* (“Devil’s Claw”)—as a purported remedy for arthritis and chronic pain. An independent scientific analysis conducted at the New York Botanical Garden (“NYBG”) concluded that your company sold a devil's claw supplement derived, in whole or in part, from a different, cheaper species that is considered less desirable: *Harpagophytum zeyheri* (the “Substitute Plant”). This would violate several provisions of federal and New York law. *See, e.g.*, 21 U.S.C. §§ 331(a), 342-343; N.Y. Agric. & Mkts. Law § 199-a; N.Y. Gen. Bus. Law § 349.

Scientists affiliated with NYBG, a leading botanical research center, used a DNA barcoding technique to identify the relevant plant source for a range of supplements labeled as containing devil's claw or devil's claw extract.¹ The NYBG study revealed widespread substitution and adulteration; of 16 U.S. made devil's claw supplements where the relevant plant

¹ DNA barcoding is a sophisticated genetic technique that relies on short, unique sequences of DNA to identify the source of plant or animal material. To carry out the NYBG study, researchers first identified unique mini-barcodes, specifically focused on the *psbAtrnH* genetic marker, to distinguish between the two *Harpagophytum* species. The study analyzed 23 supplements labeled as containing devil's claw or a devil's claw extract, including both single-ingredient supplements and complex mixtures. Five of the tested supplements were produced by non-U.S. companies and labeled for overseas sale, and are therefore excluded from the results discussed in this letter. Of the 18 supplements labeled for sale in the United States, NYBG extracted identifiable DNA from all but two of the products. (Only one of the two is labeled as an “extract” in the “supplement facts” panel.)

source could be identified—produced by 14 separate companies, including large and small firms—**100%** were found to contain the Substitute Plant, either alone (81%) or in combination with Devil’s Claw (19%). According to subpoenaed documents, this included a product sold by your company as “Devil’s Claw Root Powder,” Lot No. 1165-30437-2500 (the “Tested Lot”). Your product’s label failed to disclose the presence of the Substitute Plant. The NYBG study concluded, however, that your company’s product contained the Substitute Plant, not Devil’s Claw.

Because of the implications for consumers, we are contacting your company prior to publication of the NYBG study. This analysis, however, is far from the first to draw attention to serious quality control and compliance problems in the supplement industry. Nor is it the first red flag indicating fraud, misidentification, or other serious problems in the supply chain for Devil’s Claw, a popular and scarce plant indigenous to the Kalahari Desert; reports of raw material suppliers mixing or replacing dried Devil’s Claw root tubers with the similar-looking dried root tubers of the Substitute Plant—a cheaper plant in the same genus—are common. In this context, the results of the NYBG study are especially troubling; they suggest an industry-wide failure to take necessary steps to comply with law and ensure the accuracy of claims concerning the quality and authenticity of the supplements marketed to consumers.

As a matter of commerce, science, and law, Devil’s Claw (*Harpagophytum procumbens*) and the Substitute Plant (*Harpagophytum zeyheri*) are distinct species:

- **Commercially**, Devil’s Claw is preferred in virtually all respects, is scarcer, and commands a higher market price. After contacting several suppliers, the Office of the New York Attorney General received price quotes for Devil’s Claw root that were *two- to three-times higher* than a similar quote for the Substitute Plant.
- **Scientifically**, the two plants are separate species that can be easily distinguished in the wild. Herbalists link the purported therapeutic properties of Devil’s Claw—which are not generally accepted in the medical community or approved by the FDA—to certain naturally-occurring chemical compounds, specifically iridoid glycosides. These chemicals tend to occur naturally in Devil’s Claw at much higher concentrations. They also appear in different ratios in the two plants, and at least one chemically potent phenol glycoside in Devil’s Claw (6-acetylacteoside) is missing from the Substitute Plant. Moreover, supplements derived from the Substitute Plant—even those “standardized” to deliver a promised percentage of certain iridoid glycosides—are also likely to expose users to other chemicals that are either absent from Devil’s Claw or present at lower concentrations.²

² Certain overseas jurisdictions allow the Substitute Plant to be sold as part of the same product as Devil’s Claw. This approach has been criticized in the scientific literature due, in part, to the distinct chemical profiles of the two plants and the lack of evidence that the two are pharmacologically equivalent. See, e.g., Nontobeko P. Mncwangi, et al., *What the devil is in your phytomedicine? Exploring species substitution in Harpagophytum through chemometric modeling of ¹H-NMR and UHPLC-MS datasets*, 106 *Phytochemistry* 104-115 (October 2014) (“[O]ur results clearly demonstrate a phytochemical disparity between the two species which may impact on their biological properties. . . . The chemometric analysis results showed that the two species are not chemically equivalent, particularly, that harpagoside is not always present in *H. zeyheri*, suggesting that the therapeutic outcome may be different, thus they should not be used interchangeably until pharmacological equivalence has been confirmed.”)

- Legally, the 1992 Edition of Herbs of Commerce supplies the list of plants that may be sold in the United States commercially under particular common names. 21 C.F.R. 101.4(h).³ The relevant definition—which was reaffirmed in the more recent edition—defines devil’s claw as *Harpagophytum procumbens*, *i.e.* as Devil’s Claw. Representing any plant other than Devil’s Claw as “devil’s claw” is inconsistent with the definition codified in the Herbs of Commerce and is misleading as a matter of law. Misapplying the common name is all the more problematic where, as here, the scientific name of the non-standard species appears nowhere on the label.

Nor are we convinced that the Substitute Plant would be lawful for sale in New York or elsewhere in the United States under its proper scientific name, *i.e.* as *Harpagophytum zeyheri*. Under federal law, a manufacturer may legally sell a “new dietary ingredient”—or an ingredient that was first marketed in the United States after October 15, 1994—if it was (i) used as a source of food; or (ii) submitted to the federal Food and Drug Administration as part of a new dietary ingredient notification at least 75 days prior to initial sale. *See* 21 U.S.C. § 350b; 21 U.S.C. § 331(a); *see also* FDA Draft Guidance on New Dietary Ingredient Notifications, Docket No. FDA-2011-D-0376 76, Fed. Reg. 39111 (July 5, 2011). First, Devil’s Claw has long been marketed in the United States, including as “grapple” and “harpagophytum root.” We have seen no comparable evidence establishing that the Substitute Plant, *i.e.* *Harpagophytum zeyheri*, was sold in the United States prior to 1994, except as an unwanted adulterant.⁴ Second, the Substitute Plant appears to satisfy neither of the requirements for new dietary ingredients.⁵

In connection with an investigation arising under N.Y. Exec. Law § 63(12), N.Y. Gen. Bus. Law § 349, N.Y. Agric. & Mkts. Law § 8, and other authorities, we therefore request a detailed, written response to this letter within 10 business days. In addition to offering you an opportunity to respond to, or dispute any of the analysis above, we ask that your response cover the topics and incorporate the materials identified in the attached Appendix, including but not limited to:

- (i) The methodology and results of any testing your company performs or has performed by a third party on the Tested Lot to independently verify the results of the NYBG study;
- (ii) Your company’s plans for identifying and, where appropriate, recalling any and all non-complying devil’s claw supplements;

³ Herbs of Commerce seeks to avoid confusion in the herbal supplements marketplace by applying “a single common name in trade . . . to only one botanical name.” *Id.* at I (introduction). The common name “devil’s claw” perfectly illustrates the problem. Overseas and in non-commercial settings, that name has been used loosely to refer to numerous species, including the Substitute Plant as well as other wholly unrelated plants like *Pisonia aculeate*, *Proboscidea altheaefolia*, and *Senegalia greggii*.

⁴ To the contrary, various sources dating back many years identify the Substitute Plant as an unwanted adulterant, which was not legally exported internationally until European standards were loosened in 2003.

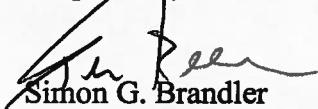
⁵ Like many traditional herbal supplements, Devil’s Claw may be administered orally, including as a tea. This does not convert it or the Substitute Plant into a source of food for purposes of the new dietary ingredient requirements.

- (iii) Your company's proposal for identifying and, where appropriate, compensating any defrauded or otherwise harmed consumers; and
- (iv) Any and all new reforms your company will implement to ensure the quality and authenticity of the herbal supplements it manufactures or distributes, including new analytical testing methods.

Notwithstanding this response, we further advise you to preserve and retain any and all documents and communications concerning the subjects addressed in this letter, including but not limited to: (i) the sourcing of ingredients for devil's claw and other herbal dietary supplements; (ii) the measures used to verify the reliability of suppliers of devil's claw and other herbal ingredients; (iii) quality control for devil's claw and other herbal dietary supplements, including awareness of misidentification of herbal products and financially motivated adulteration, with respect to raw materials or finished products; (iv) the labeling and marketing of devil's claw and other herbal supplements; and (v) the manufacturing protocols and testing methods employed to ensure the accuracy of all label and marketing claims relating to the identity, purity, potency, or other characteristics of devil's claw and other herbal supplements.

Please do not hesitate to reach out to our office with any questions or concerns.

Respectfully,



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APPENDIX

Request for Additional Documentation and Information

With your response, please furnish the following information or documentation:

- (1) For each shipment of ingredients or products your company received since January 1, 2012 that were purportedly derived, in whole or in part, from Devil's Claw and/or the Substitute Plant (the "DC Ingredients"):
 - a. The name, address, telephone number, email address, and other contact information for the supplier from whom your company obtained the shipment;
 - b. The supplier's descriptions of the content of the shipment, as they appeared on order forms, packing slips, contracts, and other written materials;
 - c. The date your company received the shipment;
 - d. The address where your company received the shipment;
 - e. The form in which the DC Ingredients arrived (e.g. powdered extract, cut-and-dried tubers, powdered whole herbs, etc.);
 - f. The address or addresses of the manufacturing facilities that produced any finished supplements containing the DC Ingredients;
 - g. The volume in kilograms of DC Ingredients received;
 - h. The total price your company paid for the DC Ingredients in the shipment in U.S. dollars; and
 - i. Copies of all product labels (front and back) for all supplements produced using the DC Ingredients in that shipment.
- (2) Copies of all audits, reviews, or other documents or communications prepared by your company or a third party to assess the reliability of any supplier who sold DC Ingredients to your company from January 1, 2012 to the present, and a description of any other verification measures not reflected in such documents and communications;
- (3) Copies of all documents and communications, including but not limited to order forms, contracts, packing slips, contracts, correspondence, or other written or electronic materials, concerning the shipment or shipments of DC Ingredients used in manufacturing the Tested Lot;
- (4) A complete description of the methodology and copies of the results of any testing or analyses your company performed or had performed from January 1, 2012 to the present on DC Ingredients or on finished dietary supplements containing DC Ingredients for identity, potency, purity, or any other characteristic, along with a

statement indicating whether any such testing could distinguish between Devil's Claw and the Substitute Plant;

- (5) A complete description of the testing or other measures your company undertook, is undertaking, or intends to undertake to determine the degree to which the products it sold since January 1, 2012 purporting to contain DC Ingredients were adulterated or misbranded, including but not limited to the Tested Lot;
- (6) The results of any and all testing described in response to Item 5 or of any other testing performed on the Tested Lot;
- (7) Copies of any and all documents or communications concerning the Tested Lot or its sale;
- (8) Copies of all documents and communications your company sent to, received from, or exchanged with any employee or agent of the federal Food and Drug Administration ("FDA") since January 1, 2012 concerning inspections of the company facilities identified in response to Item 1(f) above, including but not limited to Form 483s and your company's response thereto.
- (9) For each year from January 1, 2012 to the present, the total annual revenue or, for 2015, the year-to-date revenue your company received respectively from the sale of dietary supplements containing DC Ingredients in (i) retail sales in New York State; (ii) Internet sales to New York State residents; and (iii) the United States overall;
- (10) A proposal for identifying and, as appropriate, compensating any purchasers of devil's claw supplements your company manufactured who may have received adulterated or misbranded products; and
- (11) A complete description of improvements, safeguards, or reforms your company will implement to avoid adulteration or misbranding of herbal dietary supplements in the future, including but not limited to testing or other measures to detect and prevent the adulteration or misbranding of supplement's containing DC Ingredients.