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June 8, 2017

U.S. Food and Drug Administration
10 Waterview Blvd.
3rd Floor
Parsippany, New Jersey 07054

Re: Warning Letter, CMS#521980

Dear Sir or Madam:

We are in receipt of the Warning Letter, CMS # 521980 dated May 31, 2017, pertaining to various inspections that have taken place at Summit Nutritionals International Inc.

Additionally, we would like to thank you for the informative inspections that we have had with your compliance officers and representatives. Through the duration of our inspections, Summit has taken away recommendations and implemented new practices for operating Summit Nutritionals.

As a result of our previous inspections, we are pleased to reply to this letter with positive updates.

Per Page 1 of letter and also Comment #1 on Page 2, be advised that Summit Nutritionals has discontinued to offer/sell any Collagen products, regardless of species. We have removed any information from our website pertaining to Collagen.

Referencing Comment #1 and the BSE documentation, should Summit intend on supplying any material stemming from animal, we will have confirmation that the animal is BSE Free before making its way into commerce. We shall maintain records that demonstrate that any products do not contain prohibited cattle materials [21 CFR 189.5 (c)(1)].

Referencing Compliance Policy Guide (CPG) Sec. 560.200 Country of Origin Labeling, if Summit intends on supplying any Collagen to its customers, all measures shall be taken in order to comply with branding the product and its country of origin.

On comment #2, from this point forward we will ensure that not only we represent weight in our standard kilograms, but also in terms of avoirdupois pound and ounce in accordance with 21 CFR 101.7 (b)(1). An example of the new drum label version is attached hereto.

We thank you for accepting our response.

Sincerely,

S/ CAESAR DE PAÇO

Caesar DePaço

Droi-Kon®
summit
nutritional
international, inc.®



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FDA #: 14154026130 - Federal Tax Identification #: 22-3781843
State of New Jersey Tax Identification #: 223-781-843/000 - State of New Jersey Corporate #: 0100842076

Droi-Kon® Chondroitin Sulfate

Lot #: SN-021717

Net Weight: 25/kg (55 lbs)
Gross Weight: 26/kg (57.2 lbs)

Date of Manufacturing: February 17, 2017
Expiration / re-test date: February 17, 2020

CAS #: 9007-28-7

Preserve in tight, light resistant container.

Proudly Made in The USA