CERTIFICATE

1. Pursuant to the Provisions of Rule 44 of the Federal Rules of Civil Procedure, I hereby certify that the copy attached (as listed below) is a true copy of material on file in the Food and Drug Administration, Department of Health and Human Services, and is a part of the official records of said Administration and Department.

To Whom It May Concern letter

July 19, 2011

From Jeremy Mihalov

regarding: Summit Nutritionals Int'l Inc.

Colostrum Powder 10% IgG
Colostrum Powder 16-18% IgG
Colostrum Powder 20% IgG
Colostrum Powder 22% IgG
Colostrum Powder 25% IgG
Colostrum Powder 30% IgG
Colostrum Powder 40% IgG

2. In witness whereof, I have pursuant to the provisions of Title 42, United States Code, Section 3505, and Section 1410.20 of the FDA Staff Manual Guide, hereto set my hand and cause the seal of the Department of Health and Human Services to be affixed this 19 day of July, 2011.

Mitchell Cheeseman, Ph.D.
Acting Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

By direction of the Secretary
of Health and Human Services

"This Certificate expires on July 30, 2014"

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA ·

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

JUL 19 2011

TO WHOM IT MAY CONCERN

We have reviewed correspondence on behalf of

Summit Nutritionals Int'L Inc.
1250 Rte 28
Suites 305B, 306, 308
Branchburg NJ 08876

concerning the following products which are under the jurisdiction of the Food and Drug Administration (FDA) pursuant to the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA). These products may be exported if they meet the specifications of section 801(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)).

Colostrum Powder 10% IgG
Colostrum Powder 16-18% IgG
Colostrum Powder 20% IgG
Colostrum Powder 22% IgG
Colostrum Powder 25% IgG
Colostrum Powder 30% IgG
Colostrum Powder 40% IgG

The FDA does not approve or sanction any product or any manufacturer or distributor of such product. The Food Additives Amendment to the FD&C Act requires that we identify, in terms of chemical nomenclature, those food additives which may be safely used and the conditions under which the use of those food additives has been shown to be safe. It is the responsibility of the manufacturer or distributor to market a safe and properly labeled product (i.e., one that is safe within the meaning of the FD&C Act and the regulations promulgated under the authority of the FD&C Act, as applicable).

We can state that these products are under the jurisdiction of FDA, which has primary responsibility for the administration and enforcement of the FD&C Act. While we have not reviewed the labeling or examined the specific products that are to be offered for export, we can state that such products are eligible for export. A food additive, which is deemed a food within the meaning of section 201(f)(3) of the FD&C Act, may be exported if it complies with the FD&C Act or meets the specifications of section 801(e) of the FD&C Act (21 U.S.C. 381(e)). In accordance with the provisions of this section, a food additive intended for export shall not be deemed to be adulterated or misbranded under the FD&C Act if it:

(a) accords to the specifications of the foreign purchaser,

(b) is not in conflict with the laws of the country to which it is intended for export,

(c) is labeled on the outside of the shipping package that it is intended for export, and

(d) is not sold or offered for sale in domestic commerce.

Sincerely yours,

Jeremy Mihalov

Jeremy Mihalov
Division of Biotechnology & GRAS Notice Review, HFS-255
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition