Council for Responsible Nutrition
1828 L Street, NW, Suite 510 • Washington, DC 20036-5114
(202) 204-7700 • fax (202) 204-7701 • www.crnusa.org

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VIA ELECTRONIC SUBMISSION

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
[Docket No. FDA-2014-N-2347]

Re: Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Cosmetic Export Certificate Application Process

The Council for Responsible Nutrition (CRN) [1] is the leading trade association for the dietary supplement and nutritional products industry, representing manufacturers of dietary ingredients and of national brand name and private label dietary supplements, many of which are multinational and already actively selling ingredients, finished products and services globally.

CRN respectfully submits these comments to the Division of Dockets Management (HFA-305) of the Food and Drug Administration (FDA), in response to the Notice "Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Cosmetic Export Certificate Application Process [Docket No. FDA-2014-N-2347].

[1] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers, marketers and ingredient suppliers. CRN companies produce a large portion of the functional food ingredients and dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 150 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

REQUEST

Dietary supplement manufacturers who currently use the Export Certificate / Certificate of Free Sale that is issued by FDA's Center for Food Safety and Applied Nutrition (CFSAN) in response to submitting the requisite information into the agency, do so primarily via the electronic "CFSAN Certificate Application Process[2]."

With respect to the collection of information, FDA invites comments on these topics:

(1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;

(2) The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

CRN and CRN members agree that the proposed collection of information is necessary for the proper performance of FDA's functions and that the information will have practical utility, and we also respectfully urge FDA to improve such performance and practical utility through a more complete and revised Export Certificate / Certificate of Free Sale as outlined in the subsequent section, which would better promote exports of U.S. food/dietary supplement products. For CRN members who export dietary ingredients, the use of the same Export Certificate / Certificate of Free Sale would be advantageous in the export of said dietary ingredients.

CRN and CRN members have no reason to doubt the accuracy of the FDA estimate of burden to collect the information.

CRN and CRN members do not take issue on the quality, utility, and clarity of the information collected.

[2]http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/ucm260332.htm#Enter_a_Food_Export_Certificate

CRN and CRN members do not take issue with the amount of burden to the respondents (i.e., the requestor / exporting company) to collect and submit the information required.

EXPORT CERTIFICATE / CERTIFICATE OF FREE SALE

I. CRN and CRN members do not take issue with the currently requested information by CFSAN, i.e.:

- The name of and contact information for the manufacturer, as well as the manufacturer's state license or registration number;
- The name of and contact information for the exporting company (if different from manufacturer), as well as the exporting company's state license or registration number;
- A description of the shipment including the product, the common name, the manufacturer, and a description or additional comments;
- The name of the country to which the requester of the certificate intends to ship the product;
- The contact person, firm name and address where the requested certificate should be sent;
- The name and account number (if applicable) of the requester's preferred carrier for delivery of the certificate.
- An original or copy of the applicable product label or labels.
- The submitter's signature, the name and title of the person signing the form, as well as the date signed.

II. However, CRN and CRN members respectfully request that, in exchange for all of this relevant and requisite information provided in the certificate application process, the Export Certificate / Certificate of Free Sale be modified so it is more acceptable to the importing Ministries of Health and/or Points of Entry. More and more frequently, Ministries of Health and/or Points of Entry are having difficulties in accepting the currently provided Export Certificate / Certificate of Free Sale that is generated via the aforementioned certificate application process. These requested modifications are as follows:

a. The Export Certificate / Certificate of Free Sale should specifically provide the following statements, in addition to what is currently stated:

   - Manufacturer name and address
   - A Statement that the exporting food/dietary supplement and/or food ingredient/dietary ingredient is “Food for human consumption;”
   - A Statement that the exporting food/dietary supplement and/or food ingredient/dietary ingredient is “Freely Sold in the USA;”
   - A Statement that the exporting food/dietary supplement and/or food ingredient/dietary ingredient is legally manufactured by a registered food/dietary supplement company and/or food ingredient/dietary ingredient company that is required to comply with, and subject to inspection by the FDA for compliance with, the applicable provisions of the federal Good Manufacturing Practice (GMP) regulations for food/dietary supplements and/or food ingredients/dietary ingredients.

b. Further, from the provided information supplied by the requestor / exporting company, the Export Certificate / Certificate of Free Sale should also specifically list the following elements on the product list to be attached thereto:

   - The product information and intended country as provided by the requestor / exporting company;
   - Additional information as required by the Ministries of Health and/or Points of Entry (e.g., Country of Origin, Lot number, Expiration date, Number of units, etc.).

c. Many Ministries of Health / Points of Entry require signatures, official seals and notary imprints, such that it also would be helpful to have the Export Certificate / Certificate of Free Sale signed, sealed and notarized by FDA at time of issuance.

d. The electronic "CFSAN Certificate Application Process" also has been problematic as the limitation on characters entered per data field has truncated important information that has been difficult to submit as part of the application process. Expansion of the number of characters allowed would be very valuable.

e. A product label is required to be attached and it would be advantageous to understand any expectations for that label via detailed guidelines and provision for electronic submission of the label with the "CFSAN Certificate Application Process."

f. In this age of electronic billing and payment, there should be an option to pay for the requested Export Certificate / Certificate of Free Sale electronically in the "CFSAN Certificate Application Process."

g. It would also be advantageous if the CFSAN-generated Export Certificate / Certificate of Free Sale incorporated pagination to indicate the number of sequential pages that would be part of the Export Certificate / Certificate of Free Sale.

h. The same "CFSAN Certificate Application Process" and CFSAN-generated Export Certificate / Certificate of Free Sale should also suffice for food ingredients and dietary ingredients.

i. The requestor/ exporting company should have the option to select the type of certificate, i.e., Export Certificate or Certificate of Free Sale, to be referenced on the header of the document.

j. The amount of time, four to six weeks, required to process a submittal for the Export Certificate/Certificate of Free Sale should be reviewed for efficiency i.e., can the process be streamlined.

Incorporating the information already submitted by the requestor / exporting company and the additional statements and information requested above would greatly improve the

practical utility of the Export Certificate / Certificate of Free Sale, by better promoting export opportunities.

A drafted "mock-up" is appended (Attachment 1) based on the above requests, using the currently generated response letter and FDA Export Certificate / Certificate of Free Sale together as a template.

BACKGROUND

Some foreign countries require manufacturers of FDA regulated products to provide an export certificate for the products they wish to export to that country. A Certificate of Free Sale is a certificate that indicates that the particular product is marketed in the United States or eligible for export, and that the particular manufacturer has no unresolved enforcement actions pending before or taken by FDA. CFSAN issues such certificates for food, food additives, seafood, dietary supplements, and cosmetics. Interested persons may request a certificate by using the electronic CFSAN Certificate Application Process, which is part of FDA Unified Registration and Listing System, or by submitting a paper Form FDA 3613d for cosmetic products or a paper Form FDA 3613e for food products. CFSAN uses the information submitted to determine whether to issue the requested certificate.

Respectfully submitted,

James C Griffiths, Ph.D., DABT, FSB, CFS
Vice President, Scientific & International Affairs
Council for Responsible Nutrition

EXPORT CERTIFICATE / CERTIFICATE OF FREE SALE

Manufacturer Name

Manufacturer Address

1. Pursuant to the provisions of Rule 44 of the Federal Rules of Civil Procedure, I hereby certify that the copy attached (see attached product list) 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.

2. The product(s) on the attached list is/are freely sold in the United States of America and is/are intended for human consumption. It is/They are regulated by 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) and other related laws.

3. The products on the attached list are legally manufactured by a registered food/dietary supplement company and/or food ingredient/dietary ingredient company that is required to comply with, and subject to inspection by the FDA for compliance with, the applicable provisions of the federal Good Manufacturing Practice (GMP) regulations for foods/dietary supplements.

4. The Food and Drug Administration does not have statutory authority to approve any food/dietary supplement and/or food ingredient/dietary ingredient company or any food/dietary supplement manufacturer or distributor and/or food ingredient/dietary ingredient manufacturer or distributor of such products.

5. The referenced product(s) is /are under the jurisdiction of the Food and Drug Administration which has primary responsibility for the administration and enforcement of the FD&C Act and the FPLA and other related laws. We have not examined the specific products being offered for export or reviewed the labels. Under the FD&C Act, such product may be exported if:

a. It is not adulterated or misbranded and it meets the other requirements of the FD&C Act for marketing in the U.S.; or

b. It cannot be lawfully marketed in the U.S. but meets the requirements of section 801(e) of the FD&C Act (21 U.S.C. 381(e) because it is properly packaged and sold solely for export.

6. In witness whereof, I have pursuant to the provisions of Title 42, United States Code, Section 3505, and 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 ____ day of _____, 20##.

[NAME]
Director, Division of Dietary and Supplement Programs
Office of Nutrition, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition

By direction of the Secretary of Health and Human Services

This Certificate expires on _____, 20##.

[NOTARY PUBLIC]

[SEAL]

EXPORT CERTIFICATE / CERTIFICATE OF FREE SALE

PRODUCT LIST

Product name:

For the country of:

Additional information: [e.g. Country of Origin, Lot #, Expiration date, Number of units, etc.]*

*As required by the Ministries of Health/ Points of Entry; illustrative examples for applicants to tailor specific requests as appropriate for intended use.

[SEAL]