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PUBLIC INTEREST

Publisher of *Nutrition Action Healthletter*

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September 30, 2002

Docket No. 02D-0402
Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Room 1061
Rockville, MD 20857

Dear Sir or Madam:

Enclosed please find the original and two copies of CSPI's comments on the Final FDA Field Office Guidance, "Regulatory Procedures Manual, Chapter 9, Subchapter, "Import for Export." Please file these comments under Docket No. 02D-0402. Thank you very much.

Sincerely,

Karen L. Egbert

Karen Egbert
Senior Staff Attorney, Food Safety

02D-0402

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September 30, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

**Re: Final FDA Field Office Guidance, "Regulatory Procedures Manual,
Chapter 9, Subchapter, "Import for Export,"
67 Fed. Reg. 58,810 (Sept. 18, 2002)**

The Food and Drug Administration (FDA) has issued guidance to its field offices concerning the handling of products offered for import into the United States under section 801(d)(3) of the Federal Food, Drug, and Cosmetic Act, as amended by provisions of the Bioterrorism Act. Although the document has been issued as final guidance, the FDA has indicated that general comments on agency guidance documents are welcome at any time. On behalf of the Center for Science in the Public Interest (CSPI), we are writing to express our views on the guidance and offer considerations for future amendment.

CSPI is a non-profit consumer advocacy and education organization that focuses primarily on food safety and nutrition issues and is supported principally by 800,000 subscribers to its *Nutrition Action Healthletter*.

1. Statements Necessary To Assure That The Entire Amount Of The Product Or Article Imported Is Used or Exported or Destroyed

Under the guidance, the initial owner or consignee of an imported article to be reprocessed for export must provide FDA a statement at the time of import which, among other things, identifies the article and the initial owner or consignee. In addition, the statement must include information sufficient to identify the chain of possession of the article through each entity, including information such as product coding, lot, batch, or other identification numbers. The statements also are to be accompanied by certificates of analysis which provide the article's formulation, ingredients, components, or assay, as appropriate to the type of article.

There is one piece of information, however, that the guidance does not appear to address – the *quantity* of the article imported. The guidance would be strengthened considerably if the initial owner or consignee were also required to designate the amount of exported product received. In the absence of records identifying the precise amount of product imported for reworking and export, the FDA does not have the ability to assure that any unused article or portion of the article is exported or destroyed as required.

At domestic inspection, an inspector may seek records from the manufacturer that “establish that the entire amount of the product or article imported is used or exported or destroyed.” Since the manufacturer may not be the initial owner or consignee, those who first receive the article or product into this country should be responsible for maintaining records concerning the quantities received in each shipment.

The guidance also provides that when the initial owner or consignee of the imported article is not the importer, and the article is intended for multiple owners or consignees, each of

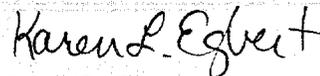
whom will serve as the initial owner or consignee for a portion of the article, the importer must submit a separate statement identifying each owner or consignees and indicating the amount of the article each is to receive. Again, however, there is no explicit requirement that the importer must provide information about the total amount or quantity that it receives. To provide better traceability and assure that all unused product is either processed, exported or destroyed, the guidance should be amended to add this requirement.

2. Certificates Of Analysis

Certificates of analysis also are required as necessary to identify the imported article. Under the guidance, they “could include documents to assure the identity of the substance and its components in the chemical and drug industries.” This language does not appear to be broad enough and should be amended to clarify that this covers the dietary supplement industry, as well as the food production industry and includes substances and components such as plants or plant matter, as well as animal parts and animal products.

We appreciate the opportunity to comment on the guidance.

Sincerely,



Karen L. Egbert
Senior Attorney, Food Safety

Caroline Smith DeWaal,
Director, Food Safety Project