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CONSULTING GROUP

February 16, 2001

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

Re: AAC Consulting Group, Inc. Comments to Docket No. OON-1633
"Marking Requirements for and Prohibitions on the Re-importation of Imported Food Products That Have Been Refused Admission into the United States"
(Published FR: January 22, 2001, Volume 66, Number 14, pages 6502-6511)

AAC Consulting Group, Inc., Rockville, Maryland represents domestic and foreign manufacturers and importers. We are supportive of the Food and Drug Administration's efforts to assure that only food products that are in compliance with the Food, Drug, and Cosmetic Act are permitted importation into the United States. To this end we encourage our clients to fully comply with all FDA laws and regulations as they apply to importing and exporting their products.

ISSUES OF CONCERN

LIMITATION OF TERM FOR MARKING REFUSED PRODUCTS

(Proposed Section 1.98) The use of the term "United States Refused Entry" does not represent all reasons for refusals correctly. Many products that are refused for "safety" concerns (safety for purposes of this rule is defined as: consuming the imported food could adversely affect a person's health) may in fact not have safety concerns. One particular example where this may be true is when a food product is refused based on a Detention without Physical Examination (DWPE).

When a foreign shipper is placed on an import alert for Detention Without Physical Examination due to a safety concern, example; Salmonella in fresh frozen shrimp, the responsibility for presenting "testimony" to overcome the appearance of the violation rests on the importer (see 21 USC 381(a)-"owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony."). Many importers choose not to present testimony because of the costs to have the product analyzed. This is especially true with small importers. The costs to test a small shipment of a product may be more than the entire shipment is worth.

The importer is faced with the dilemma of testing, reconditioning, re-exporting, or destroying the product. Testing and reconditioning may double the cost of the product, and if released, will significantly increase its cost over competing product. If the importer should decide to re-export the product, under this proposed rule, they will have to mark each container (as defined in the

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regulation) with the statement "United States Refused Entry" which does not really clarify whether the product is or is not in violation.

It appears the limitation to using only the "United States Refused Entry" does not take into account the DWPE situation, especially with small quantities of product. If the importer chooses to re-export a DWPE product that has not been proven violative, the regulation should permit an additional statement to the "United States Refused Entry" designation. We suggest addition of the statement, "Compliance with United States Law Has Not Been Determined" or similar wording be considered. The addition of this supplemental wording will show potential foreign purchasers the product may not have been rejected because of a proven safety concern. This additional statement will also advise the foreign purchaser that it will be up to them to determine if it complies with the laws of their country.

This supplemental statement does not override the intent of preventing re-importation, it does however, signify the importer chose not to determine if the product was or was not in violation of US laws.

SIGNIFICANT ECONOMIC IMPACT ON SUBSTANTIAL NUMBER OF SMALL ENTITIES

In Part VII, Analysis of Impacts: A. Introduction, FDA states "For reasons explained later in this section, FDA concludes that the proposed rule, if finalized, would not have a significant economic impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis is not required." Then, in Section E. Initial Regulatory Flexibility Analysis, 2. Economic Effects on Small Entities, FDA states: "Furthermore, this cost is borne only by small businesses that attempt to re-import unsafe, and previously refused, foods."

These statements do not appear accurate. The impact of this regulation is not limited to only those small businesses that attempt to re-import unsafe, and previously refused, foods. It actually appears to be the opposite. The majority of actions taken under this regulation will require the marking of refused goods, not the issue of re-importation of previously refused goods.

Most small importing businesses use the "Grocery Store Shopping List" ordering procedure. Specialty importers will order small quantities of many different articles from a foreign food broker and not from the actual manufacturer(s). These shipments may contain upwards of several hundred products, and each product may only contain a few cartons or less.

It is not unusual for FDA to examine many of the individual products, and as it often happens, most small importers who purchase product from a foreign food broker will not know who the manufacturer is until the product arrives. This also results in many products being detained as subject to import alerts for DWPE.

As noted in the previous statement, since the number of units purchased will be small, testing for safety concerns under a DWPE situation may cost more than product ordered. Therefore, the

requirement to mark each container (and possibly each package of product) with the "United States Refused Entry" will make decisions to re-export as expensive as testing the product.

Each product refused will require marking and supervision by FDA, or Customs, and payment of costs for this supervision. This will probably result in many good food products being destroyed unnecessarily, since the importer will not know for sure if the product they received is, or is not, actually in violation. FDA needs to re-examine the impact this rule will have on importers, especially those who import specialized foods. The consequences of such a rule on these importers does not appear to have been adequately addressed.

ENFORCEMENT ISSUES

Part II. Description of the Proposed Rule. Section F. Enforcement Issues: "If this rule is finalized with a prohibition on the re-importation of refused food, re-importation of refused food in violation of this rule would constitute a violation of 19 U.S.C. 1595a which would then permit the Customs Service to seize, forfeit, and destroy the goods after following the appropriate procedures." Thus, proposed Section 1.98(c) would prohibit: "1) Importing or offering to import any food that has been previously refused admission into the United States and marked as "United States Refused Entry"; and "2) altering, removing, tampering with, or concealing a mark."

As noted, this enforcement process may have a significant impact on importers. Since many will be ordering product from other than the actual manufacturer, the possibility of them receiving previously refused product may be a major problem. To assure they are not penalized for importing previously refused product, importers will need to protect themselves.

It is our recommendation, by making it a requirement as Section 1.98(c)(3) for the foreign shipper to include a statement on their invoices that states: "The goods shipped have not been previously shipped to the U.S. and refused admission by FDA", it will provide US importers some protection should their shipment be found to contain FDA refused product. This additional wording may also provide a means for Customs to identify foreign shippers to their counterparts in the foreign country who may also be dealing in US refused products.

Since some foods which are refused for safety issues can be reconditioned and therefore brought into compliance, to immediately recommend seizure and destruction of the re-imported refused food may not be warranted. An example of this is fresh frozen shrimp that is refused due to the presence of Salmonella. If an importer has many small lots of product and does not want to test these lots, or recondition them in the US, re-exportation to a foreign processor may provide them a way of dealing with the rejected product. If the foreign processor reconditions or reprocesses the product, example, from fresh frozen shrimp to cooked shrimp, they will still be obligated to advise any US purchaser the shrimp was from previously refused product.
Under this proposed rule, re-importation would still be a violation of the law, even if the importer can show the product has been brought into compliance by a reconditioning or

reprocessing operation (i.e., documentation of the reconditioning under appropriate foreign supervision and private laboratory testing). Thus, the agency should evaluate situations where re-importation of previously refused foods may be considered acceptable and provide guidance to its field offices to handle such situations.

AAC Consulting Group, Inc. reserves the right to submit additional comments for itself and as a representative of manufacturers and importers.

Sincerely,

Anthony C. Celeste

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President