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Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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Re: Docket No. 02N-0278; Prior Notice of Imported Food under the Public Health
Security and Bioterrorism Preparedness and Response Act of 2002
Comments of SIRVA, Inc. on Interim Final Rule

Dear Sir or Madam:

We are electronically submitting the comments of SIRVA, Inc. concerning the Interim Final Rule in the above-referenced docket. Please feel free to contact me if you have any questions or need additional information relating to these comments.

Very truly yours,



David P. Street
Counsel for SIRVA, Inc.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. 02N-0278

Prior Notice of Imported Food
Under the Public Health Security and
Bioterrorism Preparedness and Response Act of 2002

Comments of SIRVA, Inc. on Interim Final Rule

SIRVA, Inc. ("SIRVA"), a U.S. corporation with offices at 700 Oakmont Lane, Westmont, Illinois 60559, hereby submits its comments pursuant to the request of the Food and Drug Administration ("FDA") on the Interim Final Rule published in the above-referenced Docket in the Federal Register of October 10, 2003; 68 Fed. Reg. 58974. SIRVA owns North American Van Lines, Inc. and Allied Van Lines, Inc. and is one of the largest U.S. moving companies handling international shipments of household goods.

SIRVA, through its subsidiaries, Allied International N.A., Inc. ("Allied") and SIRVA Freight Forwarding, Inc. dba North American International ("North American"), provides moving services for commercial shipments of used household goods in the United States and between the United States and various foreign countries, and through its subsidiaries, Allied Freight Forwarding, Inc. (ALFW), North American Van Lines, Inc. (NOAM) and Global Worldwide, Inc. (GLOF), provides moving services for shipments of used household goods owned by US military and Government agency employees between the United States and various foreign countries. For reasons more fully set forth below, SIRVA requests that FDA exempt food in used household goods shipments

from the Prior Notice Requirements of the Interim Final Rule or, in the alternative, eliminate or modify certain of the required Prior Notice data elements for food in used household goods shipments.

Description of International Used Household Goods Shipments

International shipments of used household goods are fundamentally no different than domestic shipments. They consist of the household furniture and personal effects of individuals and families (hereinafter, “transferees”) relocating from a home in a country overseas to a new home in the United States. Often, these transferees are U.S. citizens returning home after a business assignment, military or Government Agency assignment, educational training, or an extended personal vacation in a foreign country. On occasion, transferees will pack items of food from their foreign residences and ship them with their household goods to their new residences in the United States.

Given the length of time a transportation move from overseas to the United States can take, food items in household goods shipments are rarely, if ever, perishable. They typically consist of two broad categories. First, there are items purchased abroad that can survive the transportation movement from overseas and that the transferees do not wish to waste by simply throwing away. Examples of such items are coffee, tea, pasta, beans, rice, baking ingredients, canned goods and cereals. This category may also include particular types of kinds of food items purchased in the foreign country that are not readily available in the United States. The second category includes items qualifying as “food” under the definition provided in the Prior Notice

regulations, but which also are commonly collected. Prime examples of these commodities are wine or spice collections.

An international shipment of used household goods is typically handled by Allied North American, ALFW, NOAM or GLOF - - or any other international moving company - in the following fashion. The company's agent in the foreign country, which in some cases is a corporate subsidiary and in other cases an independently owned agent, will provide the "origin services" for the move. These origin services include movement counseling, providing information on the shipment process, customs requirements, coordination of special services, document preparation, packing and arranging for the ocean transportation of the goods.¹ On moving day, the transferee's household items are inventoried, packed, and loaded into containers. In the case of large shipments, they may be loaded directly into the ocean shipping container that will transport them to the United States. In the case of smaller shipments or US military or Government agency shipments, they will be loaded at the foreign residence into smaller containers, commonly called "lift vans," and taken to the origin agent's, or a port agent's, warehouse. There, the lift vans will be consolidated with other lift vans containing household goods into the ocean shipping containers. The origin agent or port agent will book the cargo with a steamship line, which will provide the actual transportation. The ocean shipping containers are then trucked to the port, loaded on board the vessel, and carried to the United States.

¹ Sometimes, household goods shipments will be transported by air. Because this is expensive, such shipments are not common.

When household goods shipments arrive in the United States they will be handled by a "destination agent." Again, this destination agent may be a company office or subsidiary, or an independently owned agent. The household goods are cleared through Customs by a customs broker designated by Allied or North American in the case of commercial shipments, or the destination port agent of ALFW, NOAM or GLOF in the case of shipments for military or government personnel. The customs brokers are empowered to act by a power of attorney from the transferee.² The transferee is shown on the Customs entry as the importer of record. In the case of lift vans, the lift vans are removed from the ocean containers at the destination agent's warehouse. Once the goods are cleared, the destination agent arranges for the goods, still in the containers or lift vans, to be transported to their destination. Ultimately, they are delivered by a motor carrier to the transferee's new residence in the United States where the goods are unloaded, unpacked and set up in the new house.

A. An Exemption Is Appropriate for Used Household Goods Shipments

An international movement of used household goods is fundamentally a shipment of private property from the owner to himself. In terms of the Prior Notice requirements, the owner functions as owner, importer of record, and ultimate consignee. Any food items in used household goods shipments are for the personal use of the transferee. Further, transferees do not act for, or on behalf of, other entities in sending these food items to themselves. SIRVA submits, therefore, that an owner of used household goods that arranges for a translocation of his personal property from one

² US military shipments clear customs through a slightly different process and a power of attorney is not required.

residence to another is not a “shipper” for purposes of Section 801(m) of the Food, Drug and Cosmetic Act; 21 U.S.C. §381(m).

The owner of used household goods containing food articles is in a similar position as a traveler who brings food back from overseas to the United States. This type of food shipment, of course, has already been determined by FDA to be exempt from the Prior Notice requirements. 21 C.F.R. §1.277(b)(1). Like the food accompanying the traveler (which FDA has clarified does not mean physically carried by the traveler but simply accompanying him/her in the same transportation conveyance), food items in used household goods shipments are for a personal, not commercial, use and do not change ownership during the course of transportation to the United States. In a real sense, food in a used household goods shipment is even more personal than food accompanying a traveler because, although it literally travels from one personal residence to another, it remains part of the same household or home.

In this regard, SIRVA notes that FDA has determined that private residences of individuals are not “facilities” under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (“Bioterrorism Act”) and are, therefore, not required to register with FDA. Although SIRVA recognizes that exemptions under the Facility Registration regulations are not directly applicable to the Prior Notice regulations, the exemption of private residences highlights the fact that Congress was not seeking to regulate inherently private and personal import food transactions in the Bioterrorism Act. SIRVA believes the same principle should lead FDA to exempt from the Prior Notice regulations food shipments in used household goods that are moved by their owners between personal residences.

Food in used household goods shipments does not have the characteristics that have led FDA to reject other exemption requests on the basis that there is a “shipper” of the food in those cases. For example, FDA has rejected a suggestion that all food in baggage, even food that is not for the traveler’s personal use, such as samples, be exempted. FDA refused to broaden the “traveler’s exemption” because

. . .trade samples are imported or offered for import to generate sales, which is a commercial, not personal, use. Thus, there is a “shipper” when the samples are brought to the United States.

Interim Final Rule; 68 Fed. Reg. 58974, 58992. Food in shipments of used household goods, however, is for personal use and, like the traveler carrying food for personal use, the owner of such food is not a “shipper” within the meaning of the Bioterrorism Act.

FDA has also rejected a request for an exemption for “food imported for personal use which arrives in the country by common carrier.” FDA’s reasoning was that

. . .when food is shipped by an individual or business in another country to a consumer in the United States for his/her personal use (or otherwise) there is a “shipper” as that term is used in Section 801(m)(1) of the FD&C Act and defined in Section 1.276(b)(10).

Interim Final Rule; 68 Fed. Reg. 58974, 58992. The implicit assumption in this statement is that the “individual or business in another country” is different from the “consumer in the United States.” In the case of food in a shipment of used household goods, however, the owner of the food never changes. There is no sale, transfer, or transaction between two separate parties involving such food items. Thus, there is no “shipper,” when food items are merely sent from the owner to himself.

In addition, consideration should be given to the practical logistics of locating and segregating food items in shipments of used household goods. Since such food items are not commercial, they are usually small and the carton or cartons containing them may be located anywhere in a household goods shipment. Segregating any carton(s) containing the food items in response to a hold order at the U.S. port of arrival so the remainder of the household goods could move to the new owner's residence would be a very labor intensive, and expensive, effort. Also, the containers or lift vans are sealed overseas in the presence of the owner as a security measure. The integrity of the security seals would be broken, leading to the possibility of subjecting the household goods to pilferage. Finally, the effort to segregate the food would subject the household goods to additional handling and damage. These factors could lead to disruptions in the shipment of used household goods to the United States.³

In sum, SIRVA respectfully submits that food carried in shipments of used household goods that are for personal use and are simply being transferred by the owner from one personal residence overseas to another personal residence in the United States were not intended by Congress to be covered under the Prior Notice requirements of the Bioterrorism Act. FDA, therefore, should fashion an appropriate exemption for this type of food shipment in its final Prior Notice rules.

³ Congress has directed that: "The Secretary should exercise discretion in promulgating and implementing these rules to assure that prior notice requirements never become a barrier to the smooth flow of commerce." 148 Cong. Rec. H2858.

B. Elimination or Amendment of Certain Prior Notice Data Elements for Used Household Goods Shipments

In the event FDA determines, notwithstanding the highly personal nature of food shipments in used household goods, not to grant the exemption requested, SIRVA requests that FDA eliminate, or revise, certain of the data elements required in the Prior Notice for food in used household goods shipments because the information required either cannot be obtained, or cannot be relied upon, for these types of shipments.

Food items in used household goods shipments from overseas will essentially be items from the transferee's kitchen in the foreign residence. These items may not be in their original containers (e.g., flour or sugar) They may have been purchased abroad They may be in containers or packages on which all information appears in a foreign language. Further, the amount and type of information on the labels may differ from country to country or product to product. And, in many, if not most, cases, the individuals in the household to whom the food items belong will have little expertise in or detailed information about, the food products they own.

The data elements that will be most effected by these factors - - and for which SIRVA requests changes - - are as follows:

Data Element No. 5(i). The Complete FDA Product Code - - Presumably, ascertaining the correct FDA Product Code for any food item will require a proper description of the item as well as a working knowledge of how to use the FDA Product Code to properly match the description to the Code. In the case of food items in a shipment of used household goods, the only practical way of obtaining a description of each food item will be to rely on the transferee to whom the items belong There is a substantial likelihood that the descriptions of the food items supplied by the transferees

will not be precise enough to match to the FDA Product Codes. In addition, it would be extremely burdensome to transmit the food inventory prepared by the transferee to some third party for matching with the FDA Product Codes and would likely lead to substantial delays in household goods shipments. For all of these reasons, SIRVA requests that this data element be deleted for food in such shipments.

2. Data Element No. 5(iv). The Lot or Code Numbers or Other Identifier of the Food if Required by the Act or FDA Regulations, e.g. low acid canned foods (by 21 C.F.R. 113.60(c); acidified foods, by 21 C.F.R. 114.80(b); and infant formula, by 21 C.F.R. 106.90 - - For the same reasons as set forth above, SIRVA requests that this data element requirement be eliminated for food in used household goods shipments. In addition, SIRVA questions whether foreign manufacturers of food place the lot or code numbers or other identifiers of the food on the packaging and whether transferees can be relied upon to find the correct identification for this purpose. In sum, this data element also appears to be inappropriate for food in used household goods shipments.

3. Data Element No. 6. The name and address of the manufacturer of the food and the registration number assigned to the facility that is associated with the article of food. It is highly questionable whether transferees can be relied upon to properly identify the manufacturer of food items in their kitchens, much less determine the FDA registration number of each such manufacturer's facilities, even if they could determine the specific facility in which an item of food has been manufactured. The only possible source of information pertaining to this data element would be whatever label appears on any food packaging still in the transferee's possession. Therefore, SIRVA requests that this data element either be eliminated for items of food in used household goods

shipments or modified to only require the name of any manufacturer appearing on the labels of food for which labels still exist.

4. Data Element No. 8. The FDA country of production - - This generally means the country where the item was grown or manufactured, with separate rules for wild fish. For the reasons stated above, the only information a transferee would likely be able to provide for food in his/her kitchen would be information from the label of any goods for which a label is still in existence. SIRVA requests, therefore, that this data element be eliminated or merged with the data element discussed immediately above (name and address of the manufacturer) for which labels are also the only practical source of information

SIRVA appreciates the opportunity to comment on the Interim Final Rule and the consideration FDA will be giving its recommendations. Qualified and knowledgeable representatives of SIRVA with experience in the international moving industry would be happy to meet with FDA personnel at any time to provide additional information, answer questions, or help craft appropriate exemption language and/or revisions to the Prior Notice rule for used household goods shipments

Respectfully submitted,



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