

SANDLER, TRAVIS & ROSENBERG, P. A.

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THOMAS G. TRAVIS
KENNETH WOLF*
NANCY J. WOLLIN

ATTORNEYS AT LAW
THE WATERFORD
5200 BLUE LAGOON DRIVE
MIAMI, FL 33126-2022

(305) 267-9200
FAX (305) 267-5155
E-MAIL ADDRESS info@strtrade.com
WEBSITE www.strtrade.com

NICOLE BIVENS COLLINSON
SHANNON E. FURA
JO BRONSON HARRIS
WILLIAM H. HOUSTON
W. CHAD NESBIT
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MICHELLE SALEM
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ADONICA-JO R. WADA*
OF COUNSEL

†† RESIDENT IN ARGENTINA
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TRADE ADVISORY SERVICES
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October 30, 2002

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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

via federal express

General Comments Submitted on Behalf of Caribmar Forwarding Co. Guidance Documents for Implementation of Section 801(d)(3)

Dear Sirs:

This letter is written on behalf of Caribmar Forwarding Co. of Miami, Florida in response to the *Federal Register* notice of September 18, 2002 (the "Notice") announcing the availability of final guidance documents for FDA Field Offices' implementation of Section 801(d)(3) of the Federal Food, Drug and Cosmetic Act (the "Act").

SUMMARY POSITION

Caribmar is particularly concerned about FDA's interpretation of Section 801(d)(3) of the Act. The Guidance Documents include specific information on interpreting the phrases "further processing" and "incorporated" that Caribmar respectfully believes warrant reconsideration, as the Agency may be unaware of the resulting devastating impact on both the local and national economies.

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BACKGROUND INFORMATION

Caribmar Forwarding Co. has been in business for over 20 years and distributes electronic products that emit radiation, such as cellular telephones, televisions and computer monitors, into Latin America and the Caribbean.

- These products are sourced from a multinational company with its main offices in Asia and shipped from a bonded warehouse in Miami, Florida to customers located outside of the United States.
- The quantities Caribmar exports at a single time differ from those originally imported in total. For example, the initially imported shipment may include 20 containers that are then broken down into smaller quantities to meet specific needs of perhaps over 50 customers.
- The products distributed by Caribmar will not be distributed in the United States and will never be entered for domestic consumption. These items are not adulterated or contaminated nor do they pose any threat to American health or safety. These items are labeled and formulated to comply with the requirements of the foreign country to which they will ultimately be exported.
- It is not possible for Caribmar to export its products within 90 days of import. Caribmar may hold certain products for up to four (4) years, for pending customer orders, licenses and purchase orders to be perfected.
- Caribmar, and other businesses like it located in South Florida, permit the United States to compete with off-shore ports as global distribution centers. These businesses employ U.S. residents, lease U.S. warehouses, pay U.S. taxes and support a variety of supplemental industries, such as local transportation, banking, forwarding and brokerage trades.
- It is not clear whether Caribmar will be able to stay in business due to the ambiguity of the phrase “further processing” in Section 801(d)(3). The seemingly baseless exclusion of legitimate storage operations specifically set forth in the Guidance Documents may result in this well-established U.S. company having no basis upon which to import its products in a manner that permits effective and cost-effective subsequent distribution.
- If Caribmar is unable to maintain its products in the United States, under Customs supervision, for longer than 90 days, it will be forced to go out of business as the multinational company will elect to utilize facilities at a port located outside the United States (such as in Panama) to transact its distribution operations.

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DISCUSSION

○ **THE UNITED STATES MUST BE MAINTAINED AS A CRITICAL COMPONENT IN MULTINATIONAL DISTRIBUTION OPERATIONS**

As stated above, Caribmar Forwarding Co. is the exclusive Latin American and Caribbean distributor for a well-known multinational electronic product manufacturer. Over 20 years ago, this multinational corporation elected to set up its hemispheric distribution operations in South Florida to take advantage of its strategic geographic location. Were it not for the facilities offered by Caribmar Forwarding and the local marketplace, this global manufacturer would have selected a port outside the United States (such as Panama) to perform these same, critical operations, as it is beneficial for a multinational corporation to have centralized distribution facilities.

The services Caribmar currently offers to foreign manufacturers distributing into the Caribbean and Latin American enable the United States to compete for this type of international trade and distribution business. Utilizing existing Customs and FDA laws to support its business operations, Caribmar enables the domestic economy to benefit from the global operations of its primary supplier as it provides American residents and supporting businesses with salaries, bonuses, rent and commissions.

However, Caribmar’s continuing business is now threatened. Caribmar uniquely stores electronic articles for subsequent exportation to customers located outside of the United States; however, Caribmar’s operations may not qualify as the necessary amount of “further processing” required under Section 801(d)(3) of the Act. Despite the fact that Caribmar (i) stores these products under Customs’ supervision; (ii) is subject to inspection by both or either Customs and/or the FDA at any time; (iii) abides by all of the stringent rules and regulations governing Customs Bonded Warehouses; and (iv) verifies that its goods are unadulterated, marked “for export only” and comply with the importing countries’ laws and regulations in connection with same, it may, nevertheless, be forced out of the business as a result of the FDA’s interpretation of existing “import for export” regulations.

The FDA has, perhaps unintentionally, interpreted the Act in a manner that will necessarily deprive the United States of a role in the global distribution operations of multinational corporations. As a result, even though the Agency’s sole mandate is to protect the health and safety of American consumers, it has, in effect, severely threatened the health of the local and perhaps even the national economy for no apparently valid FDA law enforcement purpose. The Act must not be implemented in a manner that will deprive the United States of the economic benefits available by preserving its competitive position as a global distribution center for FDA-regulated products. To specifically prohibit activities critical to maintaining American interests in global enterprises is unjust, unfounded, unwise and contrary to the letter and intent of the law.

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The legislative history of the Act clearly evidences that it was amended to increase American competitiveness and to facilitate exportation of non-compliant goods. It is also clear that the Agency itself interpreted these amendments to preclude storage of products intended for export, although it has the discretion to have held otherwise. In the absence of specific guidelines as to permissible activities under Section 801(d)(3), the specific prohibition against legitimate storage operations will, indubitably, force multinational corporations to look offshore for creation of global distribution centers. This loss of American jobs is contrary to the very reasons the Act was amended and results in the elimination of the United States as a necessary link in existing and emerging global trade in connection with consumer goods.

CONCLUSION

While the Guidance Documents make clear that “further processing” under the Act can include a wide range of activities, the FDA has specifically prohibited storage of products in American warehouses from the range of legitimate operations permitted under Section 801(d)(3). Moreover, while articulating permissible activities such as relabeling and repackaging, the FDA has left ambiguous the spectrum of legitimate activities permitted under this “Import-for-Export” provision so that American global distributors dependent upon supply from multinational corporations may be forced out of business.

Multinational corporations have the world to choose from as they select centralized distribution outlets for their products. Regional distribution centers, such as Caribmar, are ultimately responsible for matching products supplied from the parent company with customers from within their assigned jurisdictions, thereby supporting local transportation, brokerage, banking, warehousing and related industries. If Caribmar, however, is unable to store sufficient product to meet customer needs over a substantive period of time - certainly longer than ninety (90) days - then there is no advantage provided to the parent company by having such a centralized outlet, since such expeditious shipment would be possible directly from the manufacturer itself. As a result, the multinational corporation will look to place its distribution operations in a more friendly and amenable country, where its regional distributor is able to store the products and forward them to customers as, when and in the manner requested.

The products temporarily imported by Caribmar pose no risk to American health and safety; they are not adulterated and are never sold or otherwise distributed in the domestic marketplace. To ensure the maintenance of this inventory in bonded warehouses, all protocols and regulations are strictly adhered to. The inventory is subject to consistent inventory control procedures, compliance with all safety and security measures and, in fact, is available at all times for impromptu Customs and/or FDA inspection. These products are clearly marked “for export only” and, in fact, are labeled and/or manufactured subject to recognized international standards to permit consumption in the intended country of sale.

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Caribmar would like to stay in business and would like to serve as a competitive alternative to multinational corporations looking to ports in the United States and elsewhere to serve as gateways facilitating international trade. However, without specific guidance from the Agency providing assurances that the specific types of legitimate storage and inventory manipulation activities it engages in are permissible under Section 801(d)(3) of the Act, it is very possible that this business – and many others like it --, in existence for over 20 years and providing such a valuable and legitimate service in the international marketplace, may be forced to close its doors.

If there are any questions regarding these comments -- or if the Agency would like to schedule a visit to Caribmar Forwarding Co. or other, similar businesses to learn more about the types of business activities jeopardized by Section 801(d)(3) -- it is respectfully requested that the undersigned or Lauren Perez of this office be contacted directly.

Respectfully submitted,
Sandler, Travis & Rosenberg, P.A.

By: 

Gilbert Lee Sandler

cc: Caribmar Forwarding Co.
Lauren Perez