

INTERNATIONAL ASSOCIATION OF AIRPORT DUTY FREE STORES

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Dockets Management Branch
[HFA-305]
Food and Drug Administration, 5630 Fishers Lane, Rm 1061
Rockville, Maryland 20852

Reference: Notice of Proposed Rulemaking on Registration of Food Facilities
[Docket No. 02N-0276]

Dear Sir or Madam:

The International Association of Airport Duty Free Stores (IAADFS) is pleased to provide comments on the Food and Drug Administration's proposed regulation on Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

IAADFS is the international trade organization comprised of airport duty free enterprises in the Western Hemisphere. Duty free is a unique and important aspect of international trade. It generally offers brands and products of prestigious quality in a pleasant, luxurious and exclusive environment. Airport duty free sales are directed only to international travelers, who as they leave a country may purchase certain pre-defined and limited quantities of merchandise for personal use, free of tax and duty. The industry is important to the economy, creating a positive environment for travel and tourism generally.

FDA Proposed Rule for Registration of Food Facilities

Beginning December 12, 2003, U.S. or foreign warehouses and other facilities where food is manufactured, processed or held "for consumption in the U.S." must register with the FDA. Food imports from any facility that fails to register will be subject to detention.

Application to Duty Free. Generally, the range of food products sold in a U.S.-based airport duty free store is limited. It includes packaged chocolates, candies and high-end gourmet specialty foods, as well as wines and distilled spirits. These items are sold in personal use quantities to travelers departing from the United States. Although the duty free store itself will not be required to register since it is a "retail facility", the duty free enterprise typically maintains a warehouse operation to store imported products that will be sold for export in the airport duty free store. It is unclear whether an airport duty free store's warehouse operation triggers the FDA registration requirement, as explained in the following discussion.

It is important to recognize that the food or beverage products stored in a duty-free enterprise warehouse and sold in an airport duty free store are purchased **solely** by travelers departing from the U.S. These food and beverage items are **not** consumed in the U.S. In fact, customs laws regulating the operation of duty free stores require an elaborate set of procedures to guarantee that the products sold in an airport duty free store do actually leave the country. For example, a customer who wishes to make a purchase in a duty free store must show a valid airline ticket and boarding pass before completing the purchase. To further ensure that duty free purchases are not diverted or consumed in the U.S., the duty free store must physically deliver the package of purchased items directly to the airline gate to be loaded on the plane as the passenger boards the flight. Customs imposes these and other measures to ensure that the duty- and tax-free products do not in fact enter U.S. commerce.

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Because of these unique features of duty free sales, **the food/beverages held in storage by an airport duty free store proprietor would, by definition, not be for "consumption in the U.S."** – one of the prerequisites for registration established by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. However, the proposed rule does not address whether the rules apply to the duty free industry. Given that this is a relatively small and less visible area of international trade, the FDA may very well have overlooked the special features of the duty free industry in crafting the proposed rule.

IAADFS asks the FDA to affirmatively acknowledge that a U.S. airport duty free store's warehouse operations are not subject to the registration requirements since the food items are not consumed in the U.S. Similarly, the foreign suppliers of an airport duty free store should also not be required to register [unless of course they sell food and beverage products to other U.S. entities for consumption in the U.S.].

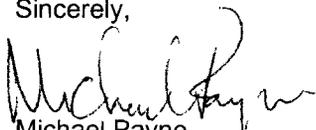
Such a conclusion is consistent with the plain words of the statute. Moreover, such a conclusion works to FDA's benefit, as well. To the extent that the FDA extends its regulatory net too broadly, it risks becoming overwhelmed and distracted by products that are not a realistic threat to the U.S. food supply, thereby diminishing its effectiveness where it matters most.

The products warehoused by a duty-free store are already subject to extensive government regulation. Virtually all the industry's food and beverage products are entered into and continuously maintained in a Customs bonded warehouse, which is regulated by the Customs Service and, in some cases, by the Alcohol and Tobacco Tax and Trade Bureau (TTB), and is covered by surety bonds. This existing regulatory framework is all the more reason why an additional layer of regulation is unnecessary.

IAADFS Recommendation: We therefore request FDA to specifically acknowledge the inapplicability of the registration requirement to airport duty free store warehouses and their foreign suppliers. In addition, FDA needs to consider the mechanism for recognizing their exempt status. An exemption would be meaningless if the failure to have a registration number causes regulators to detain the products.

IAADFS appreciates this opportunity to provide comments to the FDA and we thank you for considering our views. Please contact our Washington Representative, Jon Kent, at 202-223-6222 if there is any additional information we can provide on the duty free industry.

Sincerely,


Michael Payne
Executive Director