NATIONAL ASSOCIATION OF
FOREIGN-TRADE ZONES 2011 6 NOV 28 A6:43

November 27, 2006

U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Attn: Division of Dockets Management

Re: Proposed Rule and Request for Comments
Requirements for Foreign and Domestic Establishment Registration and Listing for Human and Animal Drugs
Docket Number 2005N-0403
RIN 0910-AA49

Dear Sirs:

The National Association of Foreign-Trade Zones ("NAFTZ") is a non-profit, trade association for individuals, public entities, and companies involved in the U.S. Foreign-Trade Zone Program. Its purpose is to promote and improve foreign-trade zones and their use. To further these goals, it often works with U.S. government regulatory and legislative bodies on the unique challenges and issues posed by foreign-trade zones. The current membership totals 835 public entities, companies, and individuals. A very significant number of these members have foreign-trade zone uses and operations that involve FDA-regulated product. As a result, the NAFTZ has worked extensively with the FDA over the years to obtain practical solutions to foreign-trade zones issues.

The NAFTZ appreciates the opportunity to provide comments on the proposed changes to the requirements for foreign and domestic establishment registration and listing for human and animal drugs. We do not agree with one proposed change and request further clarification from the agency on one point.

1. Electronic Drug Registration and Listing System: The Proposed Rule indicates that all registration and most listing information will ultimately be provided to the FDA electronically using an electronic drug registration and listing system that the FDA "intends to develop." 71 Fed. Reg. 51275, 51277 (Aug. 29, 2006). The FDA is currently working with U.S. Customs and Border Protection to develop the International Trade Data System (ITDS). The NAFTZ does not have an issue with making the current FDA drug registration and listing system electronic.

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However, it would like to emphasize and clarify that any data that must be provided to the FDA on a per shipment basis at the time of admission into a foreign-trade zone or Customs entry must be obtained through the ITDS portal. Section 405 of the SAFE Port Act of 2006 (Pub.L. 109-347), which was signed into law on October 13, 2006, requires that "[a]ll Federal agencies that require documentation for clearing or licensing the importation and exportation of cargo shall participate in the ITDS." As stated in the Act, two purposes of ITDS are to efficiently regulate the flow of commerce and to effectively enforce laws and regulations relating to international trade by creating a single portal for the collection and distribution of data. We want to ensure that the FDA is committed to build within ITDS any system that requires shipment-specific trade data.

2. Section 207.13 – Exemption From Registration and Listing Requirements: Current FDA regulations include an exemption from the registration and listing requirements for foreign establishments that admit drugs into foreign-trade zones and then re-export the drugs without the drugs entering U.S. commerce. 21 C.F.R. § 207.40(a). The FDA created this exemption in 2001 based on the premise that the registration of such entities and the listing of such drugs were not necessary to protect the public health. However, FDA is now seeking to revoke the exemption "[g]iven the additional level of import restriction imposed by the Bioterrorism Act, and the underlying security concerns that led to the [Act's] adoption." 71 Fed. Reg. at 51283.

We believe that the reasoning that justified the original exemption still applies and is not changed by the Bioterrorism Act. As already written, the exemption applies only to drugs that are admitted into foreign-trade zones and then re-exported without entering U.S. commerce. As previously determined by the FDA when it promulgated the existing exemption, such drugs do not represent a high risk to the health of the U.S. citizenry. When it passed the Bioterrorism Act, Congress distinguished risks by type of product and limited the Prior Notice requirements of the Act to food and food ingredients. See Pub. L. 107-88, § 307. Thus, it was decided at that time that security concerns were different for drug products, and these concerns were dealt with by Section 321(b) of the Bioterrorism Act, which was limited to the provision of registration information at the time drugs are offered for import.

Further, there are already several measures in place for such shipments to screen and protect the American public health. First, the Customs Advance Manifest Rule requires shippers to submit the complete name and address of the shipper, a precise description of the merchandise, and the complete name and identity of the consignee, before any merchandise arrives in the United States. See, e.g. 19 C.F.R. § 4.30. Second, while in foreign-trade zones, drugs are in an environment that is considered by U.S. Customs and Border Protection to be a "best practice" in its Customs-Trade Partnership Against Terrorism (C-TPAT) supply chain security program. Third, foreign-trade zones are required to maintain detailed inventory controls over all admitted merchandise. These

inventory controls permit the FDA to verify that all exempt drugs are actually re-exported, as required by 21 C.F.R. § 207.40(a). Finally, any currently exempted drugs in foreign-trade zones are already subject to the existing registration and listing requirements when entered out of foreign-trade zones into U.S. commerce. For these reasons, eliminating the exemption will not advance the stated requirements and purposes of the Bioterrorism Act and will, in fact, result in a higher administrative burden without offering additional protection to the health of the American public.

The NAFTZ has worked with the FDA for many years in good faith to address the unique issues posed by the U.S. Foreign-Trade Zone program. In order for the final regulations to provide the greatest benefit to the FDA, trade, and American public health, we respectfully request that the proposed regulations be revised as explained herein, and the FDA's commitment to ITDS be confirmed. Thank you for the opportunity to file these comments. We look forward to working with you in revising these regulations and our continuing relationship.

Very truly yours,

Ray Shaw

Ray E. Shaw
President

RS:bz

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