Before the Department of Health and Human Services
Food and Drug Administration

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Docket Number 2005N-0403

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Comments in Response to Proposed Notice of Rulemaking on Requirements for Foreign and Domestic Establishment Registration

Submitted by

FedEx Trade Networks Transport & Brokerage, Inc.

FedEx Trade Networks Transport & Brokerage, Inc. hereby submits these comments regarding the Food and Drug Administration's (FDA) proposed rulemaking on requirements for foreign and domestic establishment registration (Docket Number 2005N-0403).

FedEx Trade Networks Transport & Brokerage, Inc. (FTN T&B) is a customs broker and freight forwarder with a large client base, including shippers and importers of drugs covered by FDA's registration requirements. We address our comments here to the issue of the inclusion of customs brokers under the definition of persons who import or offer for import drugs regulated under the rule.

The proposed rule would require a foreign drug manufacturer to list in its registration any "Person who imports or offers for import such drug into the United States." The proposed 21 CFR §207.1 definition of "Person who imports or offers for import" to mean "… an agent, broker, or other entity, other than a carrier, that a foreign establishment uses to facilitate the import of its drug into the United States." In the August 29, 2006 Federal Register Notice of Proposed Rule, FDA noted in its description of the proposed rule that "the terms 'broker' or 'agent' include 'customhouse brokers' who facilitate importation by filing documents with U.S. Customs Service, as well as FDA and other Federal agencies responsible for the regulation of imported products."

FTN T&B is supportive of the goals of the proposed rule and suggests that a requirement for foreign drug manufacturers to include customs brokers in their registration would not assist FDA in achieving its goals. In fact the inclusion of such extraneous data as the identity of the customs broker in a foreign manufacturer's registration could hinder FDA's efforts in some cases.

Role of Customs Broker

The role of a customs broker in the supply chain is similar to that of a carrier. Carriers handle the physical movement of goods. When that involves crossing an international border, the shipment must clear customs to allow the merchandise to proceed. Customs brokers file the documentation necessary for customs clearance and, in many cases, post the required customs bonds. On occasion, a customs broker may serve as the nominal importer of record for the actual importer in order to facilitate the movement of goods.

Customs brokers, like carriers, are not the owners, buyers or sellers of merchandise. They do not broker the sale of the merchandise or have any other role in arranging the transaction that causes the movement of the goods. Only after shippers and importers have determined where and to whom they will ship the goods, do they call upon carriers and customs brokers to move the shipment. Accordingly, customs brokers are not parties "who import, or offer for import" any more than are carriers. The definition of that term

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in the proposed rule excludes carriers and it should also exclude customs brokers for the same reason.

Delays in an Emergency

Requiring foreign drug manufacturers to list customs brokers would not benefit FDA in its stated goals of monitoring drug supplies in case of urgent need due to short supply, bioterrorism emergency, or product recall. Nor would it assist FDA in identifying violations or in scheduling establishment inspections. When FDA needs to locate needed drugs in an emergency, it needs to be able to identify quickly those parties who actually posses them. That requires a listing of parties that is complete, accurate and that does not include extraneous parties who do not and never did possess the drugs FDA would be urgently seeking.

By including customs brokers as parties who import drugs or offer drugs for import, FDA risks confusing in an emergency customs brokers with parties who are actual importers or sellers of drugs. Because customs brokers would have limited knowledge of the transactions and the location of the imported drugs, FDA could waste valuable time and resources in a crisis contacting brokers in the belief that they were actual parties to the transaction who possessed or who could readily identify who did possess the drugs FDA sought.

If FDA hopes to use customs brokers to identify those to whom drugs were shipped in the United States, the only information the broker could provide would duplicate information already included in the registration. A foreign manufacturer would only list those customs brokers that it engaged to arrange customs clearance on its behalf. In those situations, the foreign manufacturer would also know the identity of the importer and would list them in its registration as well. In those cases, the identity of the customs broker would be superfluous because the consignee who received the goods would also be known.

Incomplete Information Available at Time of Registration

Any listing of customs brokers by a foreign manufacturer would be incomplete. It is unlikely that at the time of registration a foreign manufacturer would be aware of the identity of the customs broker to be used by its customer. Foreign manufacturers would not list customs brokers for those transactions in which they were not responsible for the arrangement of customs clearance. The definition of “Person who imports or offers for import” is limited to those parties whom the foreign establishment uses. Where the U.S. importer is arranging for the customs clearance or where the foreign manufacturer sells the goods to a third party who in turn ships the goods to the United States, the customs broker would not be identified in the registration and the manufacturer may not know the identity of the broker.

Any foreign manufacturer’s listing of customs brokers would further be likely to be inaccurate and incomplete because under proposed 21 CFR §207.29 (b) manufacturers

must only review and update that information on an annual basis. The customs brokerage industry is highly competitive. Importers have a wide choice of customs brokers and their relationships with brokers can be quite fluid. Any listing of brokers updated only on an annual basis stands a high possibility of being out of date well before it is updated. Use of such outdated listings increases the risk of fruitless expenditure of FDA's valuable time and resources in exigent circumstances.

Confidentiality

The proposed public disclosure of the relationships between customs broker and client raises confidentiality issues as well. Proposed 21 CFR §207.81 would make all registration information publicly available. The customs brokerage industry is highly competitive and would oppose any measure that amounts to the public disclosure of the identity of a broker's clients. Public disclosure also affects the confidentiality interests of brokerage clients. We call your attention to the confidentiality provisions of 19 CFR §111.24. The Bureau of Customs and Border Protection has interpreted those confidentiality provisions as extending to the prohibition of a customs broker from disclosing the identity of its clients. Under its proposed rule, FDA would be requiring a foreign manufacturer to publicly disclose information that a customs broker may not disclose under severe penalty.

Accordingly, FTN T&B recommends that FDA modify the definition of "Person who imports or offers for import" so that it does not include customs brokers. We make that recommendation to improve the efficiency and efficacy of the rule, to assist FDA in carrying out its functions, especially in time of emergency, and to protect the confidentiality interests of all parties involved.