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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Stuart Shapiro

**FDA Proposed Food Regulations
Dockets Number 02N-0276 and 02N-0278**

Dear Sirs:

DEXSI is a web-based, global, business to business exchange specializing in consumer products. Our members include many of the largest retailers in the world. As operators of the exchange, we provide logistics, financing, and are often the "importer of record" for many food products into the United States (both manufactured abroad and reimported). The reimported products, commonly referred to as American Goods Returned, are safe, untampered-with and in the same condition as originally manufactured by the U.S. food facility. Parallel importers, such as DEXSI, provide American consumers the benefit of a legitimate competitive marketplace, which would be denied them by domestic manufacturers and distributors who would prefer not to compete with the lower prices offered by these lawful reimporters. While we applaud the efforts of the FDA to protect America's food supply, the goals of the FDA can be accomplished in a way that is less intrusive on legitimate business. THE PROPOSED REGULATIONS, AS STATED, WILL HAVE THE UNINTENDED EFFECT OF REDUCING PRICE COMPETITION AND ULTIMATELY LEAD TO HIGHER PRICES FOR THE CONSUMER.

Importantly, because DEXSI imports genuine products manufactured by domestic food facilities, reimported in unaltered form from their original condition of manufacture, there is no question as to the safe origin of these goods. Questions regarding the handling of the goods during distribution in the parallel or reimportation market are no different than those concerns for other imported products. Nevertheless, the proposed FDA food regulations threaten the entire secondary market food industry because, without a direct relationship with the U.S. food manufacturer, much of the information required to be submitted on the Prior Notice will be impossible to obtain.

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DEXSI is concerned that the FDA did not consider the nature of the reimportation business, or consult with other companies like DEXSI, when considering possible implementing regulations. Accordingly, the following comments and suggestions are offered in the hopes that the final rulemaking more broadly reflects the various needs and types of American businesses impacted by their jurisdiction.

1. U.S. Manufacturers Must Not Be Allowed to Segment Global Marketplace

By way of background, many U.S. manufacturers distribute their food products to retailers or wholesalers (or other foreign authorized distributors) and mandate certain sales quotas for a continuing relationship. In order to meet those quotas, many facilities, both foreign and domestic, may subsequently sell their products at a discount to trading companies, or more recently business to business exchanges such as DEXSI, which then reimport the identical, unchanged products back into the 50 U.S. states. At no time have these products been tampered with or altered and at no time have they been in the hands of any unsafe facility. While it may be possible to have these foreign wholesalers or distributors register with the FDA as required under the proposed regulations, it is also more than possible that the original U.S. manufacturers will not make publicly available their registration information in an intentional effort to eliminate the lawful competition provided by reimporters such as DEXSI.

Reimporters and other parallel importers perform a valued service to U.S. consumers. Despite the efforts of some manufactures, the US Supreme Court has unanimously approved parallel marketing, through the First Sale Doctrine, as acceptable and favorable to the American consumer. The fact is, that U.S. manufacturers do not always like reimporters because, as stated above, they force the domestic manufacturers to be cost-competitive. To provide manufacturers with the ability to register only those U.S. facilities they select for distribution of their products into the U.S. marketplace and then to further provide those manufacturers with the ability to keep that list of registered facilities secret, is to intentionally create a tool for domestic food manufacturers to segment the global marketplace only for their benefit.

2. Manufacturers Must Be Required to Publish a List of Registered Food Facilities.

If the FDA does not require domestic food manufacturers to make public a list of their food facilities registered with the FDA, then, importers must be provided the opportunity to request that the FDA advise them if a particular facility is or is not

registered. Otherwise, distribution of food articles into and within the United States will be at the sole discretion of the U.S. food manufacturer that will have the ability to eliminate unwanted competition and drive consumer prices to unacceptable levels without recourse.

3. Manufacturers Must Be Required to Mark Their Products with the Identity of the Domestic Manufacturing Food Facility.

Manufacturers must be required to mark their products with the identity of the manufacturing facility. While DEXSI appreciates that the FDA, or in fact any federal agency, may not be inclined to mandate particular product labeling, in the present circumstances this may, in fact, be the only manner of ensuring that the products being domestically distributed originate from a registered facility. Because the proposed regulation allows domestic manufacturers to specifically designate which of its many factories will be permitted to manufacture food for U.S. consumption, and, as a result, only food emanating from those facilities will be allowed to be reimported back into the country, then the FDA must require that manufacturers clearly disclose on every product label the place of manufacture. In this way, consumers can verify whether the product being distributed is from a registered facility, the FDA can verify that the product being imported is from a registered facility and the international trader, itself, has the means to determine whether or not the product may be lawfully reimported for consumption back into the U.S.

4. FDA Should Create Its Own Bonding Regimen To Protect Known Importers

It is unclear how or whether non-compliance with the FDA's pre-arrival protocols will impact upon existing Customs bonds held by U.S. importers. However, in the wake of what appears to be the creation of tools benefiting only the large domestic food manufacturers, it is respectfully suggested that the FDA may wish to institute its own bonding requirements for importers to validate the safety and integrity of their food supply chains. In this way, should the FDA question information contained on a Prior Notice or question the lack of such information, the importer may insist that while such questions are being addressed, so long as such questions do not impact upon the admissibility of food articles, the products be conditionally released so as not to compromise product freshness or integrity.

Importers unwilling to secure this additional bond may be unable to continue operating within the current marketplace, but for those accepting such an additional burden they will be satisfied that safe and lawful grocery items will not be unnecessarily

held at the border while additional efforts are undertaken to ensure the FDA that the information provided on the Prior Notice is sufficient. This assurance may come, for example, in the form of coordinated efforts to obtain missing registration information or from voluntary testing and sampling of imported merchandise. To deny even conditional release of food articles for failure to produce registration information that U.S. manufacturers may elect to intentionally keep secret -- or because the product was manufactured in a facility owned by a U.S. manufacturer but which that manufacturer intentionally elected not to register with the FDA or not to publicly disclose -- serves no purpose other than to eliminate lawful competition in the U.S. marketplace, create unnecessary entry delays and create backlogs at U.S. ports of entry.

5. Registration Numbers Not Required on Prior Notices

DEXSI, in its capacity of "Reimporter", only imports goods identical in all respects to that which is distributed in the United States under authority of that identical U.S. food facility. Accordingly, so long as a Reimporter advises FDA where the food was produced, under whose authority it was manufactured and who may have handled the food during its round trip back into the country, there would appear to be no reason to require further information from the Reimporter to verify the safety of the subject food article.

It is certainly true that because a Reimporter has no direct relationship with the U.S. manufacturer it may, itself, have no means to verify the registration numbers of all facilities involved in the intended business operation. Nevertheless, the Reimporters are willing and able to provide the FDA with all information they have on hand to verify the safety and integrity of the subject food article. Recognizing the importance of Reimporters' continued business to U.S. consumers who deserve a freely competitive marketplace and, moreover, the stated willingness to provide FDA with a separate and additional bond securing continued adherence to all safety requirements under U.S. laws and regulations, the FDA should be willing to waive the requirement for registration numbers on the Prior Notice. This is especially true in light of the fact that the Agency, itself, is unwilling to make such numbers publicly available to legitimate importers.

The FDA is able to inspect any imported article and/or to verify via its own information system that the product has been processed only by registered facilities and/or that it is otherwise safe for U.S. consumption. To require that Reimporters provide this information to the FDA itself as the only means of facilitating lawful entry and distribution is unreasonable -- especially given the natural urge of the domestic manufacturer to deny Reimporters such as DEXSI the information it may need to legally import these otherwise admissible products.

6. FDA must guarantee confidentiality of Prior Notice submission

While both Congress and the FDA specifically promised the confidentiality of the information gathered during the registration process, the proposed regulations make no such promise in connection with the information detailed in the Prior Notice submissions. While in no manner mitigating the importance of the information that may be learned as a result of registering a facility with the FDA, there is little question that the information required in the Prior Notice is much more detailed and proprietary.

The Prior Notice mandates disclosure of everything from grower to purchaser, including importer, consignee, brand name, trade name, shipper, carrier, port of arrival, etc. The finalized regulations must specifically and conspicuously promise that this information will remain confidential even withstanding requested disclosure through FOIA or, again, all forms of legitimate competition will be compromised as a result of these regulations. There is not a single business operation that will risk disclosure of supplier, source, purchaser and related information to interested domestic competitors by a requirement of pre-arrival, prior notice and such a risk must not be a possibility even if only through ambiguity of existing regulations. Again, the final rulemaking must specifically and conspicuously promise the confidentiality of the information contained within the Prior Notice submissions.

Conclusion

DEXSI understands and appreciates the complexity of promulgating regulations that will protect American consumers, comply with congressional mandates and facilitate continued American business growth. However, respectfully, DEXSI believes that the proposed food regulations appear not to have considered that substantial portion of the U.S. market that depends upon the lawful importation and distribution of food articles through sources not specifically sanctioned by the U.S. food manufacturer. To eliminate this lawful competition by regulations that provide domestic businesses with the means to intentionally segment global marketplaces is to deprive American consumers of safe food products at competitive prices. It is respectfully hoped that the FDA will consider the business of lawful importation of American Goods Returned as it considers the form and content of its final rulemaking.

In this regard, it is respectfully requested that the undersigned be contacted directly prior to final rulemaking in order that it may help the FDA meet with members of the parallel marketplace prior to the drafting of those regulations. Respectfully, if the FDA does not make an effort to consider the needs of the legitimate parallel marketplace as it drafts its final regulations, it will be intentionally disregarding a much-needed and important segment of the American marketplace in favor of the oftentimes louder voices

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of U.S. manufacturers. American consumers deserve the competition companies such as DEXSI offers and DEXSI believes that the FDA can meet its obligations under the BioTerrorism Protection Act of 2002 without eliminating this legitimate form of U.S. industry.

Respectfully submitted,

Harvey Shapiro
Chief Financial Officer
DEXSI

By: _____

A handwritten signature in black ink, appearing to read "Harvey Shapiro", is written over a horizontal line. The signature is stylized and cursive.