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Title: FDA Guidance for Products from Tianjin, CN

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To: Automated Broker Interface

FDA is informing US importers of intended increased surveillance of certain FDA-regulated products imported from the industrial center Binhai New Area in Tianjin, China.

On August 12, 2015 a chemical explosion occurred at the Tianjin Dongjiang Port Rui Hai International Logistics Co., at the industrial center named Bihhai New Area. Tianjin Dongjiang Port Rui Hai International Logistics Co. Ltd. was a storage and distribution center of containers with hazardous chemicals: sodium cyanide (NaCN), toluene diisocyanate (TDI) and calcium carbide (CaC2), all of which pose direct threats to human health on contact. NaCN in particular is highly toxic.

In order to verify the products are not contaminated from the explosion, FDA will be requiring submission of entry and shipping documents (bills of lading, air waybills, commercial invoices, etc.) for entries of human and animal food products, human and animal drug products, and medical devices which are indicated as having originated from, stored in, or transited through the industrial center Binhai New Area in Tianjin, China. FDA will review the documents to determine if the shipment was in the Tianjin, China area on or after August 12, 2015. Products that left the Tianjin, China before August 12, 2015 should need no additional review other than the routine FDA admissibility review.

Human and animal food products, human and animal drug products, and medical devices that left the Tianjin, China area on or after August 12, 2015, will require additional information in order to make an admissibility decision. FDA is requesting importers (or their entry filers) submit the following information related to the products they are importing:

1. If you are not the end commercial user of the product, provide information identifying all known recipients of the product.

2. Explain the physical disposition of the product at the time of the explosion and for the time between the explosion and when it left the city of Tianjin, including the following:

(a) Where was the product located (geographical location) at the time of the explosion and in the aftermath of the explosion through the present?

(b) How was the product packaged (primary, secondary packaging, wrapped pallet, shipping container, etc.) at the time of the explosion and in the aftermath through the present?

3. Explain whether your firm conducted a risk assessment to determine the impact of the August 12 explosion on the safety of your product. And, if so, explain your methodology and the outcome of your assessment.

4. Explain what testing has been conducted or is planned to be conducted on the product to identify contamination associated with the August 12 explosion?

Importers are advised that it may speed FDA's review process if entry documentation is provided in a timely manner; and, for those shipments indicated for examination or sampling, if location and availability information is provided in a timely manner.

To facilitate receipt and review of information, FDA strongly recommends submission of documents via electronic means. FDA's Import Trade Auxiliary Communication System (ITACS) is designed to improve communication between FDA and the import trade community and facilitate the electronic submission of documents to FDA.

Instructions on how to use ITACS to submit documentation and information to the FDA can be found at the following link: http://www.fda.gov/ForIndustry/ImportProgram/ucm296314.htm. Questions or comments on how to submit documents, or about ITACS in general, can be directed to itacssupport@fda.hhs.gov

Questions regarding this action by FDA can be directed to Division of Import Operations, 12420 Parklawn Drive, ELEM Room 3109, Rockville, MD 20857 telephone: (301) 796-8969.

Questions related to the entry processing of specific entries should be directed to the FDA District covering the port of entry.