CATARACT CUSTOMHOUSE BROKERAGE, INC.

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*IMPORT & EXPORT SPECIALISTS*

June 30, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Subject: Comment on Establishment and Maintenance of Records (Docket Number 02N-0277)

Dear Sir/Madam:

We respectfully wish to submit comments on the Proposed Regulation of Establishment and Maintenance of Records (Docket Number 02N-0277) under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Our comments on the "Establishment and Maintenance of Records" Regulation, concern the definition of importer, customhouse broker involvement, duplication of records, the burden on larger companies and the compounding problems at the border.

The FDA uses the word importer, but does not give a definition of the word. The FDA has to define whether they mean the importer of record or the initial United States recipient when the merchandise enters the country. Each definition could have a completely different effect on who is responsible for the establishment and maintenance of records.

The customhouse broker involvement should be limited to what the broker already does. The broker already has the entry as a record of the shipment, along with submitting documents physically or electronically to the FDA. The broker would not be able to keep

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any more in-depth records than that because the broker has no further knowledge about the shipment.

The duplication of records is an issue that if not addressed will impede present and future shipping extensively. The FDA has to work with U.S. Customs and other government agencies to see what type of records are being kept now. Working together the government agencies can review what records are being kept now and what records are lacking. The FDA, along with the other government agencies, can build, establish and maintain from what is already in place. To have an extensive duplication of records will put the focus in the incorrect areas, which could leave an opening for something detrimental to happen because due diligence was not used in all areas.

Past situations have demonstrated that the FDA already has a policy and good track record for finding and refusing adulterated products and products that could pose a problem to the American public. This new policy, therefore, raises questions such as, how is any new policy for the establishment and maintenance of records going to improve on the existing record keeping? How is the FDA from reviewing records (paperwork) going to find a specific shipment that could pose a threat to the American public?

The foreign shipper is in the best position for the most accurate records. The shipper sees the merchandise and often receives it from the actual grower or manufacturer. They are also the most knowledgeable in regard to adulterated or contaminated merchandise and are in the position to stop the shipping of the merchandise. The United States company and customhouse broker are not in that position.

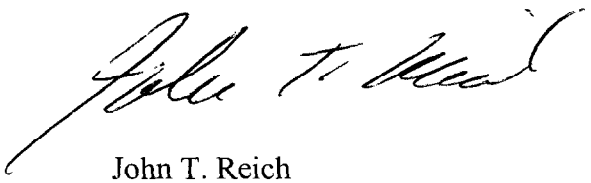
For larger companies, however, this would put still another undue burden on them in regard to cost and manpower. Based on information supplied by FDA in earlier correspondence, we estimate that a large company, which ships the equivalent of one truck every 20 – 30 minutes, would have to hire several people to handle the extra work between both the prior notice and the record keeping. The cost would be approximately an extra $160,000 per year.

Every foreign country should be handled differently depending upon the risk the country and their products pose. Does the FDA have any such plans to do this, i.e. Canada should be treated differently from Mexico and Mexico should be treated differently from El Salvador, etc.?

Finally, the more restrictions and paperwork involved in shipping will mean an extensive waiting time at the border. Therefore, with these new restrictions, a new and more effective border policy for the FDA has to be established.

Thank you for the time and consideration of our comments.

Respectfully,



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