Submission by Tracon Consultants Ltd. to

Food and Drug Administration
Agency Information Collection Activities
Proposed Collection
Comment Request

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Docket No. 2006N-0202
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This submission is to address the Food and Drug Administration's invitation for comments on whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.

We refer the FDA to our previous two submissions that can be found at the following internet link: http://www.fda.gov/OHRMS/DOCKETS/dockets/03d0554/mostrecent.htm under document number EC9. Our concern is regarding goods transshipped securely through the United States from one point in Canada to another point in Canada. When we say securely we refer to goods shipped by a Customs-Trade Partnership Against Terrorism (C-TPAT) or Partners In Protection (PIP) certified exporter, and a C-TPAT certified carrier, with a C-TPAT approved bolt seal on the container. PIP is the Canadian equivalent to the C-TPAT program. It is our submission that in this situation prior notice is not necessary for FDA to perform its functions for the following reasons:

- the goods do not enter the commerce of the United States nor disembark in the United States nor remain in the United States;
- the parties responsible for the goods (exporter and carrier) are classified as low-risk having undergone the rigorous and thorough approval and compliance processes of U.S. Customs and Border Protection (CBP) and Canada Border Services Agency (CBSA).

The FDA is responsible for determining whether shipments arriving are of risk in order to protect the nation's food supply against terrorist attacks and other public health emergencies. Shipments entering the United States under the circumstances described above have already been determined to be low risk and therefore the requirement that they be subject to the Prior Notice requirements is redundant. This means Prior Notice is not required in this situation for FDA to properly perform its functions and the information that would be provided to FDA will have no practical utility.

We would like to comment as well on the burden of the Prior Notice requirement not in reference to the context in which it is presented in the Federal Register Notice but rather in the context of our own experience. The current requirements eliminate the option of transshipment through the United States as described in our previous submissions due to the nature of the shipments and the inability to meet the Prior Notice time and data requirements. The burden, therefore, in our particular case, is an increased annual transportation cost of $60,000 that results from east (Ontario) to west (British Columbia) routing through Canada. Burden in hours is incalculable as Prior Notice is not an option.

We again request, therefore, that such shipments be exempt from Prior Notice requirements as they are redundant, these shipments are low risk and the requirements are not necessary for FDA to fulfill it's functions.

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