July 28, 2006

Comments of the Government of Canada on the information collection provisions of Food and Drug Administration (FDA)'s regulations under the *Public Health Security and Bioterrorism Preparedness and Response Act* of 2002 (Bioterrorism Act) requiring that the agency receive prior notice before food is imported or offered for import into the United States.

Docket No: 2006N-0202
FR Doc.: E6- 8311
May 31, 2006 (Volume 71, Number 104)

RE: Agency Information Collection Activities - Prior Notice of Imported Food

The Government of Canada welcomes the opportunity to provide comments on the FDA's prior notice information collection provisions under the Bioterrorism Act, as notified under Docket No. 2006N-0202 and published by the FDA, in the Federal Register of May 31, 2006, (Volume 71, Number 104). Specifically, Canada is responding to the invitation to submit comments concerning ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The notice indicates that the Bioterrorism Act and applicable regulations require that prior notice of imported food be submitted electronically using the US Customs and Border Protection's (CBP) Automated Broker Interface of the Automated Commercial System (ABI/ACS) or the FDA Prior Notice System Interface. It notes, as well, that much of the information collected for prior notice is identical to the information collected for the FDA's importer's entry notice, which is collected electronically via CBP's ABI/ACS at the same time the respondent files an entry for import with CBP.

Many exporters of shipments containing multiple products, such as the dietary supplement industry, have indicated to the Government of Canada that exporting to the United States is no longer economically viable because of the current mode of application of the Prior Notice Rule. This is also true of transporters who have discontinued transhipping through the US either to another country or back into Canada due to the costs involved with prior notice.

In comments submitted July 13 2004, the Government of Canada requested that the FDA implement all possible measures to reduce the cost to responders by minimizing the data entry required by the CBP system and the FDA prior notice system interface. As well, Canada's comments stressed that there are areas in Canada which do not have access to high speed Internet, where the need to minimize data entry time is critical, to reduce the likelihood of the line being dropped. In our July 2004 comments, Canada also argued that the U.S. Customs and Border Protection *Free and Secure Trade /Customs-Trade Partnership Against Terrorism* (CBP FAST/C-TPAT) programs are sufficiently robust to make them fully effective in managing the risk of intentional adulteration of products covered by the FDA regulations.

Based on the above, Canada requests that the FDA implement the following measures to minimize the burden of the collection of information on responders for the purpose of prior notice.

1) Canada requests that, to reduce duplication, the FDA and CBP work together to develop integrated data elements for both regular and FAST/C-TPAT shipments which would meet both FDA and CBP requirements. The information required should be submitted once and then transferred to the other agency as required. Currently, AStandard Manifest@ data elements must be transmitted to CBP prior to arrival in order to clear a regular shipment, and the APreferred Manifest@ data elements must be transmitted to CBP in order to clear a low risk FAST/C-TPAT shipment. In addition to these CBP transmissions, a separate Prior Notice transmission to FDA, with a different data set, is required to meet the prior notice requirements.

2) Canada requests that both the FDA and CBP systems be simplified to more efficiently enter data which is common to all products in the shipment. For instance, information such as importer and shipper, which is common to all products in a shipment, should only need to be entered once.

3) Canada requests that the FDA work cooperatively with CBP such that exporters of transhipments through the US would not be required to enter additional information for FDA Prior Notice purposes, and that information required would be entered solely through the CBP process. Transhipments, including both those originating in Canada and entering the US for purposes of export to a third country, as well as Canadian shipments routed through the US and returned to Canada, are transported under CBP control in bond and information is entered under the CBP Automated Commercial system. It is Canada's view that the CBP reporting rules and process are adequately designed to capture the information necessary to identify transhipments that may pose a risk as defined by FDA.

Canada urges the FDA to take Canada=s comments, including those submitted previously, into consideration in developing the Final Rule for Prior Notice. Canada=s objective is to continue to recommend a final rule that achieves the objectives of FDA and the United States Congress in a manner that does not create unnecessary rigidities and disruptions to legitimate low risk trade between our two countries.

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