

Canadian Embassy



Ambassade du Canada

501 Pennsylvania Ave., N.W.  
Washington, D.C. 20001

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

ATTN: Docket No. 2002N - 0278

Joint Food and Drug Administration - Customs and Border Protection Plan

The Government of Canada welcomes the opportunity to provide comments on the above-referenced *Joint Food and Drug Administration - Customs and Border Protection Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes* (Joint Plan) as published by the Food and Drug Administration (FDA) Department of Health and Human Services, in the Federal Register of April 14, 2004 (Volume 69, Number 72).

If you have any questions on the submission, please contact the undersigned at 202- 682-7787.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'R. Krystynak'.

Ronald Krystynak  
Agriculture Counsellor

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**Comments of the Government of Canada on the Joint Food and Drug Administration - Customs and Border Protection Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes under the Prior Notice of Imported Food Rule under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002**

**Docket No:** 2002N-0278  
**FR Doc.:** 04-8515 Filed 4-9-04

**RE:** Joint FDA/CBP Plan

## **1 Introduction**

The Government of Canada welcomes the opportunity to provide comments on the above-referenced *Joint Food and Drug Administration - Customs and Border Protection Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes* (Joint Plan) as published by the Food and Drug Administration (FDA) Department of Health and Human Services, in the Federal Register of April 14, 2004 (Volume 69, Number 72).

The Government of Canada is pleased that the FDA is working with Customs and Border Protection (CBP) to synchronize advance notice timeframes for information concerning shipments arriving by land via road or rail, and by air. As Canada noted in our comments provided to FDA on December 22, 2003, synchronized time frames between CBP and FDA for prior notification will help to avoid confusion and unnecessary disruptions to trade between our two countries.

The Joint Plan describes the activities and implementation schedule to be followed by FDA and CBP in order to achieve the goal of a uniform, integrated system with coordinated timeframes for import prior notice information. The Government of Canada supports this objective and views the following comments as instrumental to its achievement.

## **2 Implementation Schedule**

Canada recognizes that review and reallocation of resources take time. However, we are concerned that publication of the Final Prior Notice Rule is dependant upon the completion of the proposed review period which is scheduled for March 2005. During this time full enforcement of the interim final Prior Notice Rule will be in effect, without having taken into consideration Canada's comments previously submitted.

Canada requests that sufficient resources are allocated by FDA and CBP to implement the Joint Plan in a shortened review time period.

### **3 Assessment of Resource Requirements**

A key activity of the Joint Plan is to assess the resources required and available to “receive, review, and respond to prior notice submissions,” as set out in section 21 USC 801(m)(2)(A) of the Federal Food, Drug, and Cosmetic Act.

Canada requests that the assessment of the resources encompasses all potential resources available at the border, including those of the Department of Homeland Security (DHS). We also request that the FDA investigate the possibility of extending the current Memorandum of Understanding with DHS to make better use of DHS resources at the border to enforce FDA Rules.

### **4 Level of Industry Compliance**

Canada is concerned that the implementation schedule of the Joint Plan may be delayed due to industry non compliance with the Interim Final Prior Notice Rule.

We are willing to work with the FDA to increase the level of Canadian industry compliance through outreach and education activities. In order to do this, Canada requests that the FDA provide to us, on a timely basis, detailed information concerning non compliance by Canadian industry.