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From: joe.rosario@gov.ab.ca  
Sent: Tuesday, December 23, 2003 3:59 PM  
To: fdadockets@oc.fda.gov  
Subject: Docket Number 02N -0278

Please find attached comments from the Government of Alberta regarding Establishment of Prior Notification Requirement for All Imported Shipments - Docket Number 02N-0278.

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EMC146

December 23, 2003

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

**Re: Establishment of Prior Notification - Docket Number: 02N-0278**

The Government of Alberta welcomes the opportunity to comment on the Interim Final Rule regarding Prior Notice published in the US Federal Register on October 10, 2003 under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (The Bioterrorism Act).

The Government of Alberta appreciates that in drafting the interim final rules the Food and Drug Administration (FDA) has addressed a number of our concerns regarding timelines for prior notice and persons authorized to provide notification. These rule changes are clearly more reasonable and reflect the large volumes of just-in-time shipments at the Canada-US border.

The Government of Alberta supports the US initiatives to counter bioterrorism and ensure food safety while meeting international trade rules. Notwithstanding the progress to date, the following comments are intended to improve the rules and avoid unnecessary disruption of Canadian exports to US markets.

***Bilateral Security Initiatives***

Under the Smart Border Plan, many Canadian exporters enrolled in US Customs programs such as the *Customs-Trade Partnership Against Terrorism (C-TPAT)* and *Free and Secure Trade (FAST)*, which reduce the risk of bioterrorism. The Government of Alberta suggests that the FDA consider expedited treatment for Canadian companies that participate in these voluntary risk based programs.

***Prior Notice Requirements – Repeated Business***

The proposed regulations appear to overlook one type of trading relationship - shipments directly from commercial exporters to consumers. Some Alberta companies ship products to US consumers in two different ways: direct home delivery to consumers and direct to consumers through e-commerce.

The proposed FDA regulations do not specifically deal with repeated shipments to individual consumers and the high volume of prior notices that will be generated under the proposed rules. The FDA should directly address this type of trade in its regulations. The Government of Alberta suggests that a single weekly summary of all shipments by a company to individual consumers or a summary of orders received would adequately address this type of commerce.

***Transshipments***

The Government of Alberta questions the prior notice requirement for transshipments to other countries through the US. This requirement is unnecessary and goes beyond the scope of the Bioterrorism Act. We understand that Customs Border Protection (CBP) currently requires advance information for transshipments in order to conduct risk assessments for the purposes of ensuring health, safety and security. Since these products would never be made available for consumption in the US and are under control of CBP during transit, we recommend that all transshipments through the US be exempt from the Prior Notice rule.

***Phase-In Period***

The commercial trade environment between Canada and the US is quite extensive, involving perishable goods and just-in-time deliveries requiring a large volume of prior notices. Given this volume of trade unforeseen difficulties may arise in the transmission and processing of prior notices. The Government of Alberta requests that, should the situation arise, the FDA maintain the flexibility to extend the phase-in period.

We hope that the expedited trade for low risk exporters, commercial shipments directly to consumers, transshipments and the possible extension to the implementation period will ensure continued smooth and beneficial trade between Canada and the US.

The Government of Alberta appreciates the opportunity to comment on this regulation as both of our countries are collaborating to ensure the safety of our food supply.

Sincerely,



Dr. J.A. Rosario, Executive Director  
Policy Secretariat, Alberta Agriculture,  
Food and Rural Development

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