



Division of Dockets Management (HFA-305)
Food & Drug Administration
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1236 TO MAY 14 2004
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Attention: <http://www.fda.gov/dockets/ecomments>

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Fonterra (USA) Inc Submission on Department of Health and Human Services US Food and Drug Administration " Public Health Security and Bioterrorism Preparedness and Response Act of 2002"

Docket No 02N-0276

Registration of Food Facilities Section 305

30 April 2004

Fonterra (USA) Inc (formerly NZMP (USA) Inc d/b/a/ Fonterra (USA), 635 North 12th street, Suite 101, Lemoyne, Pennsylvania 17043 USA, is a wholly-owned subsidiary of Fonterra Co-operative Group Ltd., Auckland, New Zealand. Fonterra Co-operative Group is one of the largest companies in New Zealand, accounting for 20% of the New Zealand GDP and 7% of New Zealand' s Total Exports by Value, and is one of the top ten largest global dairy traders across open borders in the world (July 2003 figures) Fonterra Co-operative Group Ltds supply chain stretches from New Zealand shareholders' farms to customers and consumers in 140 countries. The Co-operative collects over 13 Billion litres of milk per year and manufactures and markets over 1.8 million tonnes of product annually.

Fonterra (USA) imports a wide range of these New Zealand origin dairy products, subject to regulations administered by the Food and Drug Administration, accounting for approximately 45% of U.S. dairy product imports (2002 data), accounting for over \$500M of imported value per year, supplying some of the largest and most well-known brands in America. We are therefore heavily impacted by the FDA Bioterrorism Act' s Interim Final Rules on Facility Registration and Prior Notice submission.

Fonterra (USA) supports the efforts of the FDA in its implementation of the Bioterrorism Act and its intent to safeguard the food supply in the United States. We share in the FDAs interest in this goal and applaud the efforts made, including the to-date modifications that have been implemented as a result of comments such as these from industry. We herewith respectfully submit further comments to the Interim Final Rules as we continue to partner with the FDA in this matter. Our current comments are more fully elaborated as we have now had several months experience with the provisions as currently implemented.

Fonterra (USA) sincerely thanks FDA for its efforts to improve upon the interim final rules on facility registration to balance security requirements with business realities. We look forward to further modifications to make this process the most secure and least burdensome possible.

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Regulatory Compliance

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Cc: Glenn Kane, VP Sales, Fonterra (USA) Inc

Cc: Don Learmonth, President & CEO, Fonterra (USA) Inc

Facility Registration Comments

- The current facility registration system has no provision to prevent duplicate or inaccurate registrations. We request that the FDA cross-reference submitted facility information to state or other records to prevent identity theft and/or fraudulent registrations, nor provisions to notify legitimate firms of suspected errors.
- We request that FDA prompt registrants every 60 days to verify that the FDA system-information is accurate; depending solely on internal control provisions may allow for inadvertent errors. Since the omission of submitting this information in a timely fashion has been deemed a prohibited act we request that the FDA take on the responsibility for these verifications.
- We request that appropriate penalty provision be made for inadvertent clerical errors.
- A shipper' s facility registration number may be a required data element in the prior notice (PN) submission, however there is no provision on the Form 3537 for a shipper. We request that the form be amended to include a category for shipper.
- An animal is considered food but a farm is exempt from facility registration. We request clarification.
- There is no facility registration requirement for transshippers, however CF7512s (T&E, I.T.s) require a PN to be filed. This cannot be accomplished without the corresponding facility registration number. Moreover, in the case of T&Es and I.T.s, there is no designated submitter. We request that T&E and I.T. transactions be exempt from PN requirement. (See also Prior Notice comments).
- The Facility Registration IFR requires that a facility register with the FDA prior to MPPH activity. We request that a grace period be permitted allowing for registration prior to shipment activity.
- If an " Owner, Operator, or Agent in Charge" appoints someone else to act on their behalf, does this assignation need to be documented? For a Corporation, who is deemed to be the owner, operator or agent in charge? Please clarify.
- Since the Interim Final Rules are not fully tested, we request that the rules be maintained as interim final for a longer period of time with phased implementation.