AFIA

AMERICAN FEED INDUSTRY ASSOCIATION

December 23, 2003

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

Re: Prior Notice of Imported Food; Docket No. 02N-0278

The American Feed Industry Association (AFIA) appreciates this opportunity to submit comments regarding the Food and Drug Administration's (FDA) interim final rule on prior notice of imported food. 68 Fed. Reg. 58,974 (Oct. 10, 2003).

AFIA is the national, not-for-profit trade association for feed and pet food manufacturers, ingredient manufacturers and suppliers, equipment manufacturers, and other firms that supply goods and services to the feed industry. AFIA's nearly 600 corporate members manufacture 75 percent of the nation's primary commercial feed. Because AFIA members are subject to the interim final rule, AFIA offers these comments on their behalf.

The interim final rule is far more workable than the original proposed rule. FDA is to be commended for working hard to adapt the prior notice requirement to the needs of international trade. AFIA believes that a few issues still require clarification or adjustment in the final rule.

1. **FDA should define the term "trip number."**

FDA's interim final rule requires that a prior notice submitted for an article of food arriving by truck, bus, or rail must include a "trip number." The interim final rule does not define this term. AFIA requests that the final rule clarify what type of number FDA has in mind.

2. **FDA should be aware that prior notices may list U.S. manufacturing facilities.**

In some cases, after animal feed manufactured in the United States is shipped to a foreign country, a sample may be sent back to the United States for analysis. Under the interim final rule, the prior notice for the sample will be required to include the name and FDA registration number of a U.S. manufacturing facility.

2002N-0278 C 264

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AFIA hopes that FDA's Prior Notice System Interface and the Bureau of Customs and Border Protection's (CBP) ABI/ACS/OASIS system will not automatically reject a prior notice that contains a U.S. manufacturing facility and facility registration number.

3. A shipment of trade samples should require only one prior notice.

It is customary for overseas feed manufacturers to ship quality assurance (QA) samples to the United States. For example, forage samples from Canada may be sent to the National Forage Testing Lab in the United States for analysis, and feed mills in Canada may send QA samples to labs in the United States. A single shipment of QA samples may include samples taken from many different farms or feed mills. Under a strict reading of the interim final rule, each sample from each different farm or feed mill would require a separate prior notice. AFIA believes that requiring, for example, 30 prior notice submissions for one shipment consisting of 30 QA samples would be an unnecessary and excessive burden. We request that only one prior notice be required for each shipment of QA samples.

4. AFIA urges FDA to protect prior notices from public disclosure.

The prior notices submitted to FDA under the interim final rule will contain information about feed ingredients and sources of supply that may often rise to the level of confidential business information, defined by FDA as "valuable data or information which is used in one's business and is of a type customarily held in strict confidence." 21 C.F.R. § 20.61(b). AFIA urges FDA to create some mechanism whereby interested parties may assert protection from public disclosure under the Freedom of Information Act for information contained in prior notices that they believe is confidential business information.

We appreciate this opportunity to comment.

Respectfully submitted,

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