



**LAND O LAKES®
Feed**

July 8, 2003 7 1 '03 02 17 00:10

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

RE: Docket No. 02N-0277

**Establishment and Maintenance of Records under the Public Health Security
and Bioterrorism Preparedness and Response Act of 2002**

Notice of Proposed Rulemaking

Land O'Lakes Feed is a major manufacturer and distributor of animal feed, including medicated feed, and therefore has a vital interest in the agencies effort to promulgate regulations for the implementation of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Land O' Lakes Feed also represents cooperative feed manufacturers and dealers doing business as Land O'Lakes/Farmland, Purina Mills, and other independent businesses manufacturing and selling animal feed.

Land O'Lakes Feed overall is very supportive of the regulations that would be established by this notice of proposed rulemaking. In general, the regulations mirror what is actually being practiced today in the way of record keeping. There are however, a issue that is of concern, and that same issue has and continues to be a problem in FDA's BSE rule 21 CFR 589.

We therefore refer to Section 1.326 (d)(1) of this proposed rule that provides for exemption from record keeping requirements for retail establishments from section 1.345 records of those that buy retail product from them. Retail establishments would not include persons that manufacturer a product that they sell. May small rural feed mixers also have a retail outlet in their facility that sells bag feed over the counter to final purchasers for feeding to their own animals, and not for resale. Maintaining records of these sales would be a burden and is not a practice today. We do not believe the establishment of a recording keeping requirement would enhance public safety in the area of bioterrorism. We there respectfully request the following change that would add a new exemption as follows:

- sec . 1.1.327 (d)(3) Retail establishments that manufacture bag feed for animals that sell such bag feed from their facilities at retail to feeders for use with their own animals, and not for further sale.

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Inclusion of this exemption for feed manufacturer retail sales will not be in keeping with present day requirements, and will not compromise food safety from bioterrorism.

Sincerely,

A handwritten signature in black ink, appearing to read "Jan", with a large, sweeping loop at the beginning.

Jan Campbell
Manager, Regulatory Services