



LAND O LAKES[®] Feed

August 26, 2003

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

**RE: Docket No. 93P-0174
Requirements for Liquid Medicated Animal Feed and Free-Choice
Medicated Animal Feed
Proposed Rule**

Land O'Lakes Feed is a major feed manufacturer in the United States representing both commercial feed mills operating under several different feed product brand names, and independent feed manufacturers manufacturing brand feed under cooperative agreements. Land O' Lakes feed facilities manufacture both liquid and free choice feeds. Land O' Lakes Feed holds several unique liquid feed and free choice feed approvals approved via master files and supplemental NADA's, and therefore will be affected by this proposed rule.

The proposal primarily articulates the requirements for mill licensing and approval procedures for liquids and free choice feeds. Land O'Lakes Feed is in full agreement with the proposal and applauds the agency for moving forward with these needed revisions to the present rules that provide an update to the present regulations that are out of date and also provide needed relief for the industry.

Where the agency does not publish the formula and/or specifications of a liquid or free choice feed in the drug's regulation because of trade secret information entitled to protection under section 301 (j) of the act, the agency says: "We intend to provide the NADA holder and the MF holder with a certified letter citing the approved formula and/or specifications of the free-choice feed where that information is not published. The letter will demonstrate to FDA inspectors that the free-choice feed is manufactured using an approved formula and/or specifications."

Land O' Lakes Feed has a couple of concerns relative to the intent of the above statement. The proprietary information must not be shared with the NADA holder, as it is confidential to the MF holder, and therefore should remain protected from the NADA holder. Therefore, the certified letter containing the proprietary information should only be issued to the MF holder.

We agree with a certified letter to the MF holder that can be shared with the inspector to facilitate inspection, but there are presently many approved free choice and liquid feeds

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approved via a MF where no such certified letter has been provided to the MF holder. In these cases, the information is contained in the information filed with the agency in the master file. Further, we would assume that the intent of the above statement is to also provide a certified letter for liquid feeds where confidential information is in the master file, and not in the regulation for the drug. The same issue holds true for these liquid feed past approvals.

We respectfully request that the agency either go back and issue such certified letters for all previously approved free choice and liquid feeds where the formula and/or specifications of the approval are in a master file and not in the drugs regulation, or make it clear that the certified letter only applies to free choice feeds and liquid feeds approved after a certain date. We can see problems with facility inspections if this is not clarified.

The original citizen petition also provided for appropriate stability data for liquid feeds. Presently, guidance documents outline stability data for liquid feeds, and such guidance documents are not a part of this proposed rule. Land O' Lakes is also very concerned that the data requirements for both liquid and free choice feeds continues to drift towards drug approval requirements, rather than what is appropriate for feeds. Land O' Lakes urges the agency to revisit these liquid and free choice feed stability requirements, as well as consumption data and manufacturing chemistry requirements articulated in that original citizen petition, for revisions to the present liquid feed and free choice feed guidelines. Our company representatives would be willing to meet with agency representatives in this regard at the agencies convenience.

Land O' Lakes Feed appreciates this opportunity to comments.

Sincerely,



Jan Campbell
Manager Regulatory Compliance