



LAND O LAKES[®] Feed

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

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December 2, 2005

Docket No. 2005N-0329
Regulatory Identification No. (RIN) 0910-AF60
Designation of New Animal Drugs for Minor Uses or Minor Species

Land O'Lakes Purina Feed LLC ("LOLPF"), together with its subsidiaries, is a major manufacturer and distributor of animal feed. LOLPF also works with cooperative feed manufacturers and dealers marketing brands, such as LAND O LAKES[®] Feed products and Purina Mills[®] products, and other independent businesses manufacturing and selling animal feed who are stakeholders in the U.S. food safety system. LOLPF manufactures animal feeds for multiple species including minor species and Zoo animals and, therefore, will be impacted by the above-referred rule. While we are fully supportive of the proposed rule and it's intended purpose to provide needed medications to minor species animals, the rule does not go far enough in providing needed relief.

LOLPF is very concerned that much confusion now exists relative to the proposed rule. There is tremendous need for use of drugs administered through animal feed at Zoo's, animal theme parks, and laboratory animals of various types for various purposes including animal breeders. These establishments have veterinarians on staff, and the animals are not used for food purposes. Many, if not most, of these establishments now believe that if they have a veterinarian prescription, then they can have any drug they might need added to the animal feed under this proposed regulation. Most are not familiar with the laws relative to the exclusion of animal feed from the extra label uses for animals. However, the need continues to exist.

The agency presently allows a veterinarian, under specified conditions, to prescribe an approved major species drug in animal feed to be used for a minor species. LOLPF filed comments with the agency previously on several occasions, including comments relative to the Compliance Policy Guide in December of 1999. Following comments filed by interested trade associations and feed companies, a meeting was held with the Center for Veterinary Medicine (CVM) to review the concerns of our industry. A major point that was presented to CVM at the meeting was consistent with the above referenced comments that said, the feed approved for a major species may not be adequate for the minor species because of nutritional and/or physical form issues. In our previous comments we listed a number of animal species that need medications where a major species diet may not be adequate. However, the policy issued did not provide needed

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relief nor does this proposed rule, which is the subject of these comments. LOLPF continues to believe that the minor species feeder, and the veterinarian, must be able to adjust the nutrition and/or physical form of the major species feed to be suitable for the nutritional and/or physical form needs of the minor species. In addition, for improved efficacy, the level of medication may need adjustment under the direction of a veterinarian.

Neither the designation nor conditional approval provisions of MUMS change the existing standards for the approval or the use of drugs in the feed of minor species. (The conditional approval provisions simply delay the application of the existing effectiveness standard for up to 5 years.) Therefore, LOLPF believes that it is the indexing provisions of the legislation to which we must look to help resolve the problem we have identified on several occasions.

The indexing provides for feed use products as well as dosage form products. As a potential sponsor of such products, we would have the responsibility of convincing a qualified panel of experts that a particular feed use product would be safe and effective for one or more intended uses in a non-food minor species and assuring that FDA agrees with that assessment. Such a feed use product could, but also should, be manufactured in a physical form and with a nutritional composition tailored to the minor species for which it is intended. This could be overly burdensome on both the agency and the feeder/feed supplier.

Considering that relief for our identified concern is needed now, we ask that the agency make the following procedure available under the indexing provision of MUMS in the proposed rule:

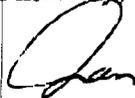
- Cover letter fully explaining the requested action (feed sponsor)
- Letter from the establishment owning the minor species, which lists their need for the medication, lists each animal species, number of animals, sex, and treatment regimen.
- Letter from veterinarian for each drug prescribed, number and sex of animals, level of use, and duration/directions for use for each animal species.
- Label facsimile for feed(s) to be used to deliver medication under the veterinarian prescription
- Statement that the animals are not to be used for food.
- Statement by feed sponsor that the manufacturing facilities are in full compliance with 21 CFR part 225.
- Statement on the feed label that the feed is not for sale, but a customer formulated feed for the specific establishment identified in the indexing provision application.

The actual manufacture of a drug under this provision would be a customer-formulated diet, as defined by the Association of American Feed Control Officials in their Official Publication, and have needed medication added in accordance with a major species

approval coupled with a veterinarian recommendation. The drug, drug level, directions for use, and indications for use would all continue to be consistent with the major animal FDA approval as published in the drugs CFR regulation, except for changes in the dosage level as deem appropriate by the veterinarian.

LOLPF appreciates this opportunity to comment. Our staff stands ready to provide whatever further information FDA might believe to be useful in this regard, and we would be most happy to meet with the agency to help in the development of needed provision for the relief needed.

Sincerely,



Jan Campbell,
Manager Regulatory Compliance
Land O'Lakes Purina Feed LLC