



**LAND O LAKES®  
Feed**

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

Docket No. 2006N-0067  
Regulatory Identification No. (RIN) 0910-AF67  
Index of Legally Marketed Unapproved New Animal Drugs for Minor Species  
HHS  
Proposed Rule

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 its intended purpose to provide needed medications to minor species animals, the rule does not go far enough in providing needed relief.

Indexing envisions the drug sponsor spending an average of \$9,100 per minor use request to provide for needed medications. However, there are many minor species use needs that won't even justify that expenditure. Land O Lakes can share these needs that presently take place under INAD 9526 G-0043 where theme park animals are in need of anthelmintics and Zoo animals in needs of MGA to help prevent unwanted pregnancies. In these cases, the drugs are approved for major species uses, but not for these minor species animals.

In the above mentioned INAD, attached are the combined feed tonnage and the costs to the theme park and/or zoo for the wormers (Ivermectin, Pyrantel Tartrate and Morantel Tartrate) and contraceptive (Melegestrol Acetate). The combined tonnage numbers and amount charged includes the drug (which is provided at cost to the feed buyer). The purpose in providing these numbers is to show that, in some cases, there is simply not enough profit money in these minor species needs to support an expenditure of \$9,150 per minor species need.

We are not suggesting that the proposed indexing provision be changed, we are suggesting that an exemption be provided where sales would not support the \$9,150 cost for indexing.

The drug can presently be administered through extra label drug use provisions through dosage administration other than feed. However, the feed route of administration can be done ONLY BY ADMINISTERING THE MAJOR SPECIE FEED NUTRITIONAL FORMULATION AND

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PHYSICAL FORM. The feed can not be re-formulated to provide for the physical form needs, nor the nutritional needs of the minor species. In the situation we are discussing, the drug sponsor is not willing to spend money on such a minor use, and thus this situation will continue if this proposed rule is not in some way amended to provide for this need.

In addition, LOLPF is very concerned that much confusion now exists relative to the present CVM extra label use policy. 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 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.

These indexing provisions certainly can provide the relief needed for the needs discussed above in these comments, however, only if the drug sponsor or a stake holder is willing to fund the effort at an estimated average cost of \$9,100. LOLPF definitely believes that the indexing provision should be the first means of providing the relief needed. However, if the drug sponsor or other interested stake holder is not willing to move forward with the funding needed for indexing of the minor species drug need, and if the drug needed is presently approved for a major species use and that drug would be eligible for extra label drug use provisions if not a feed use, then such minor species drug need should be provided relief through regulatory discretion by the agency. Perhaps the agency could provide an economic trigger on feed sales, that if such sales were to exceed \$100,000 per proposed minor species use, then indexing for such use would be required, and the exemption would not be available for such use.

We therefore respectfully request that the agency make the following procedure available under the indexing provision of MUMS in the proposed rule if no interested stake holder is willing to fund the indexing provision of this proposed rule.

Alternatively, if the minor species drug need does not justify the cost of indexing:

- Cover letter fully explaining the requested action (feed sponsor)
- Letter from the establishment owning the minor species animals, which list their need for the medication, list 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.
- Statement from the Veterinarian that the drug use for the minor species animal(s) is the same as that approved for the major species in terms of conditions of use, use level, and duration of use.
- 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

ATTACHMENT

(Year 2005)	Total Tons*	Selling Price *
• Wormers		
○ Mazuri ADF-16 (Ivermectin, Pyrantel Tartrate)	77.11	\$35,594
▪ Mazuri ADF-16 10 g/ton Ivermectin		
▪ Mazuri Omaha Zoo Hoofstock 10 g/ton Ivermectin		
▪ Mazuri ADF-16 1000 g/ton Pyrantel Tartrate		
• Contraceptives		
○ Mazuri ADF-16 (MGA)	39.73	19,728
▪ Mazuri ADF-16 0.5 mg/lb MGA		
▪ Mazuri 0.1 mg/lb MGA		
▪ Mazuri 0.7 mg/lb MGA		
 (Year 2004)		
• Wormers		
○ Mazuri ADF-16 (Ivermectin, Pyrantel Tartrate)	99.33	\$45,635
▪ Mazuri ADF-16 10 g/ton Ivermectin		
▪ Mazuri Omaha Zoo Hoofstock 10 g/ton Ivermectin		
▪ Mazuri ADF-16 1000 g/ton Pyrantel Tartrate		
▪ Mazuri ADF-16 2,225 g/ton Pyrantel Tartrate		
• Contraceptives		
○ Mazuri ADF-16 (MGA)	38.51	20,986
▪ Mazuri ADF-16 0.5 mg/lb MGA		
▪ Mazuri ADF-15 0.1 mg/lb MGA		
▪ Mazuri ADF-16 0.7 mg/lb MGA		
 (Year 2003)		
• Wormers		
○ Mazuri ADF-16 (Ivermectin, Pyrantel Tartrate)	65.23	\$31,102
▪ Mazuri ADF-16 10 g/ton Ivermectin		
▪ Mazuri ADF-16 1000 g/t Pyrantel Tartrate		
▪ Mazuri ADF-16 2,225 g/ton Pyrantel Tartrate		
• Contraceptives		
○ Mazuri ADF-16 (MGA)	66.05	34,023
▪ Mazuri ADF-16 0.5 mg/lb MGA		
▪ Mazuri ADF-16 0.1 mg/lb MGA		
▪ Mazuri ADF-16 0.7 mg/lb MGA		

\*Includes combined wormer/contraceptive INAD product tons and selling price for year