

Purina Mills, Inc.

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

December 1, 1999

(Docket No. 99D-2638)
Use of Medicated Feeds for Minor Species
Draft Compliance Policy Guide
For comments to our comments dated October 1, 1999

Purina Mills filed comments relative to the above reference draft Compliance Policy Guide. Since filing those comments Purina believes that the policy should make a distinction between food animal and non food animal minor uses. Purina continues to believe that FDA policy must provide for needed medications to all animals consistent with animal and human safety considerations. Clearly however, there is a human safety difference between food, and non food animals. In the case of non food animals, the issue is simply animal safety, and not human safety. Purina believes that this distinction deserves separate treatment by the agency in the proposed policy guide.

The policy as written definitely provides needed relief for some food and non food animals. However, in many cases the feed approved for a major species will not be adequate for the minor species because of nutritional and/or physical form issues. In our previous comments Purina listed a number of animal species that need medications where a major species diet will probably not be adequate. That list was: "Addax, Aoudad, Bison, Blackbuck Antelope, Defassa Waterbuck, Eland, Elk, Deer, Zebra, Impalla, Llama, Mini Horses, Mouflon, Nilgal, Rhino, Watusi, Water Buffalo, Gnu, Miniature Mule, Gensbok, Wild Burrow, Mutjac, Kudu, Giraffe, Perbelly, Camel, Pigmy Goats, Pheasant, Rabbit, Monkey, lizard, peacock, Yellowhead Amazon, Ducks, Prarie Dog, Raccoon, Wolf, Couti, Virvit, Goats, Sugar Glider, Macaw, Parrot, Cockatiel, Tiger, Lion., Cougar, Jaguar, Ostirch, Emu, Rhea, and laboratory rats and mice. This list is certainly not meant to be all inclusive.

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In considering the difference between the safety concerns of food and non food animals, Purina suggests that a non food animal feeder should have the ability to obtain 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 food animal FDA approval as published in the drugs CFR regulation.

In the above scenario, after the non food animal owner and his veterinarian determine that a medication is needed for the health of the animals. A medication is selected by the veterinarian from medications presently approved for major species animals at levels and use rates approved in the drugs CFR regulation. The animal owner then contacts a feed manufacture requesting a customer-formula feed be manufactured with the veterinarian's recommended drug level. A customer-formula feed is defined by AAFCO as; " a commercial feed which consists of a mixture of commercial feeds and/or feed ingredients each batch of which is manufactured according to the specific instructions of the final purchaser." The labeling for the feed will be consistent with the major animal species approval, but the feed ingredients and feed guarantees will be those requested by the non food animal owner. To accomplish this the following changes will be needed to the draft Compliance Policy Guide.

- In the "Guidance" section, "Under this guidance, the agency ordinarily will not consider regulatory action if:" add a new item 2, and make the present 2 number 3. Number 2 would then read: 2. Any medication approved for use in a major or other minor animal species may be customer formulated (as defined by the Official Publication of the Association of American Feed Control Officials) and labeled according to its approved labeling, as described in the code of Federal Regulations (21 CFR part 558) for a non food minor species. In such cases the feed label must show the drug level, indications for use, feeding directions and claim consistent with the major animal species approval (21 CFR part 558). However, in addition the feed label may show the minor animal species for which the feed has been customer-formula manufactured with feed guarantees and a ingredient listing."
- In the "Regulatory Guidance" section of the guide, the sentence "If the feed is not formulated and labeled in accordance with the approved conditions of use as described in the code of Federal Regulations, add the words, "and the Official Publication of the Association of American Feed Control Officials."

These changes will permit zoo animals, and other non food minor species animals to receive medication through recommendations of their veterinarian, yet also receive appropriate nutritional and physical form needs in their diet.

Again, Purina is very supportive of the agencies efforts to bring needed medication to all minor species animals consistent with animal and human safety considerations. Purina believes that this Compliance Policy Guide, amended as suggested above, will be a big step toward accomplishing these objectives. Without the suggested modifications, most non food minor species animals will not receive needed medication through feed, which in many cases for these type animals, is the only practical means of providing medication.

Purina Mills appreciates this opportunity to comment and trusts that the agency will find our comments useful. If there is need for further information or clarification of our comments, please phone me 314 768-4492.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. E. Broyles', written in a cursive style.

R. E. Broyles, Director
Regulatory & Quality

cc American Feed Industry Association
National Grain and Feed Association

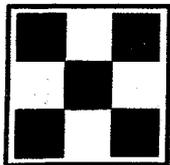
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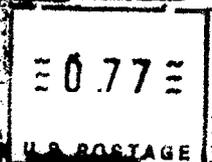
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