

Food and Drug Administration
Rockville MD 20857

AUG 25 2004

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Mr. Alexander S. Mathews
President
Animal Health Institute
P.O. Box 1417-D50
Alexandria, Virginia 22313-1480

Re: Citizen Petition #91P-0434

Dear Mr. Alexander:

This is a final response to Citizen Petition 91P-0434, which the American Veterinary Medical Association and the Animal Health Institute jointly submitted on October 21, 1991, and amended on March 6, 1992. The petition requested that the Commissioner of the Food and Drug Administration (FDA, the agency) enact a series of changes in regulatory policies, guidelines, and administrative procedures that would facilitate the approval of additional therapeutic claims for drugs used solely under the supervision of licensed veterinarians.

On October 5, 1992, the agency provided an interim response to your citizen petition, noting that the Center for Veterinary Medicine was actively exploring alternative data requirements for prescription animal drugs. At the time, FDA expected these efforts to result in new guidance on the animal drug approval process. Since that correspondence, there have been significant changes in the laws, regulations, and policies relating to the approval of new animal drug products.

The action requested in your petition is organized into three parts and our response to each is as follows:

Efficacy Considerations

Your petition proposes several sources of data and information that could be used to establish a dose or a dose range for an initial new animal drug claim or for subsequent claims. Since 1996, FDA has issued a number of relevant regulations significantly impacting the animal drug approval process pursuant to the Animal Drug Availability Act (ADAA, Public Law 104-250). The ADAA, enacted on October 9, 1996, was designed to increase the number of animal drugs on the market by allowing for more flexibility in the drug approval process (including labeling) without compromising FDA's mission to protect the public health. As a requirement of its implementation, the ADAA mandated that the agency, among other things: (1) publish regulations to further define "adequate and well-controlled" studies and "substantial evidence" and (2) take into account the proposals contained in your citizen petition (91P-0434/CP). Pursuant to this mandate, FDA issued regulations defining "adequate and well-controlled" studies and "substantial evidence of effectiveness" (21 CFR 514.117 and 514.4).

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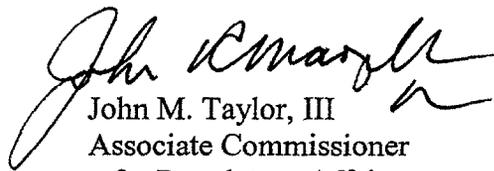
Safety Considerations

Your petition recommends using the highest dose of a proposed dose range for target animal safety testing and tissue residue testing. FDA believes your recommendation is consistent with the Agency's policies and practice. The concept of dose range labeling is described in 21 CFR 514.4(b)(2)(i). CVM Guidance for Industry #33 entitled "Target Animal Safety Guidelines for New Animal Drugs" states that drug tolerance studies should be based on the "maximum proposed dose." It also states that drug toxicity studies should be based on the "maximum recommended drug use level." CVM Guidance for Industry #3 entitled "General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals" states that total residue depletion studies should employ the dose that is the "highest intended treatment level." It also states that metabolism studies in target animals should be "dosed at the maximum use level requested." In the case of a dose range, or in the case of a drug with more than one approved dose, FDA has typically allowed more than one withdrawal period on the labeling. As an example of this kind of labeling, we refer you to the original Freedom of Information (FOI) summary for NADA 141-063 dated May 31, 1996, and the supplemental FOI summary for this NADA dated June 4, 1998.

Professional labeling for Prescription Uses of OTC Products

Your petition requests establishment of an agency policy which would permit sponsors to inform veterinarians, by means of "professional labels," of FDA-approved prescription uses of OTC animal drugs. In our October 1992 letter to you we stated: "With respect to the concept of 'professional' labeling which would relate to, but not accompany, currently approved over-the-counter animal drug products, we feel that such an approach would be generally unworkable." This is still our position for two reasons. First, we believe the proposed "professional labels" would be inconsistent with the Federal Food, Drug, and Cosmetic Act (the Act), such as sections 502(c) and (f). Second, this approach to labeling gives us serious concerns about the "professional labels" being misdirected to lay person in possession of the OTC labeled product. For these reasons, the professional labeling component of your petition is denied.

Sincerely yours,


John M. Taylor, III
Associate Commissioner
for Regulatory Affairs

cc: HFA-305 (Docket 91P-0434)