

hearing (NOOHs) on proposals to withdraw approval of NADAs for all penicillin-containing premix products intended for use in animal feed and for certain subtherapeutic uses of tetracyclines (chlortetracycline and oxytetracycline) in animal feed. Some of these products are listed in § 558.15. These NOOHs are still pending and nothing in this document constitutes a bar to subsequent action to withdraw approval on the grounds cited in the outstanding NOOHs.

G. Marketing

Marketing of the products that are the subject of this document, and which are approved, may be continued, provided that, on or before (see **DATES**), the holder of the application submits a signed Form FDA 356v *New Animal Drug Application* and complete product labeling (including specimen labeling for Type B and Type C medicated feeds) conforming to the applicable findings of effectiveness.

Supplemental NADAs that are filed in response to this document and comply with the requirements set forth will be approved, and documents will be published in the **Federal Register** amending the approval regulations in accordance with the approval and identifying the sponsor under section 512(i) of the act.

III. Notice of Opportunity for Hearing

On the basis of all available data and information, the Director of CVM is unaware of any adequate and well-controlled clinical investigation, conducted by experts qualified by scientific training and experience, meeting the requirements of section 512 of the act that demonstrates effectiveness of the drugs listed in section II of this document, for their labeled indications of use other than the effective claims as stated in this document.

Therefore, notice is given to the sponsors of the NADAs for the nine animal drug products or combination uses described in section II of this document, and to all other interested persons, that the Director of CVM proposes to issue an order under section 512(e) of the act withdrawing approval of the NADAs providing for any claims other than those classified in this document as effective. The ground for the proposed withdrawal is that new information about the drug products, such as that provided by the NAS/NRC reviews, evaluated together with the evidence available at the time of approval, show there is a lack of substantial evidence that the drug will have the effect it purports or is

represented to have under the conditions of use prescribed, recommended, or suggested in the labeling. An order withdrawing approval will not issue with respect to any application supplemented in accordance with this document to delete any indication for use lacking substantial evidence of effectiveness.

This notice of opportunity for hearing encompasses, in addition to the ground for the proposed withdrawal of the approvals, all issues relating to the legal status of the drug products subject to it, e.g., any contention that any such product is not a new animal drug within the meaning of section 201(w) of the act (21 U.S.C. 321(w)).

In accordance with section 512 of the act and part 514 (21 CFR part 514) and under the authority delegated to the Director of CVM (21 CFR 5.502), a sponsor and all other persons subject to this document are hereby given an opportunity for hearing to show why approval of the applications should not be withdrawn.

A sponsor or any other person subject to this document who wishes to request a hearing must file: (1) On or before (see **DATES**), a written notice of appearance and request for a hearing, and (2) on or before (see **DATES**), the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact to justify a hearing as specified in § 514.200. Any other interested person may also submit comments on this document.

Procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for a hearing, submission of data, information, and analyses to justify a hearing, other comments, and a grant or denial of a hearing, are contained in § 514.200 and 21 CFR part 12.

The failure of a holder of an approval, or any other party subject to this document, to file a timely written appearance and request for hearing as required by § 514.200 constitutes an election not to avail itself of the opportunity for hearing and a waiver of any contentions concerning the legal status of any such drug product, and the Director of CVM will summarily enter a final order withdrawing the approval. Any such drug product labeled other than for the effective claims identified in this document may not thereafter be marketed lawfully, and FDA will initiate appropriate regulatory action to remove any such drug product from the market. Any new animal drug product marketed without an approved NADA is subject to regulatory action at any time.

A request for hearing may not rest upon mere allegations or denials, but

must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that there is no genuine and substantial issue of fact that precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person who requests a hearing, making findings and conclusions, and denying a hearing.

If a hearing is requested and is justified by the sponsor's response to this notice of opportunity for hearing, the issues will be defined, an administrative law judge will be assigned, and a written notice of the time and place at which the hearing will commence will be issued as soon as practicable.

All submissions under this document must be filed in four copies. Except for data and information prohibited from public disclosure by law, the submissions may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m. Monday through Friday. This document is issued under section 512 of the act and under the authority delegated to the Director of CVM (21 CFR 5.502).

IV. Environmental Impact

The agency has determined under 21 CFR 25.33(g) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

The collections of information requirements for this document are covered under OMB control numbers 0910-0032 and 0910-0184.

Dated: August 1, 2003.

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