overpayment by requesting that the Department of the Treasury reduce any amounts payable to the overpaid individual as refunds of Federal income taxes by an amount equal to the amount of the overpayment;

(c) The conditions under which we will waive recovery of an overpayment under section 1631(b)(1)(B) of the Act;

(d) That we will review any evidence presented that the overpayment is not past due or not legally enforceable;

(e) That the overpaid individual has the right to inspect and copy our records related to the overpayment as determined by us and will be informed as to where and when the inspection and copying can be done after we receive notice from the overpaid individual that inspection and copying are requested.

§ 416.582 Review within SSA that an overpayment is past due and legally enforceable.

(a) *Notification by overpaid individual.* An overpaid individual who receives a notice as described in § 416.581 of this subpart has the right to present evidence that all or part of the overpayment is not past due or not legally enforceable. To exercise this right, the individual must notify us and present evidence regarding the overpayment within 60 calendar days from the date of our notice.

(b) *Submission of evidence.* The overpaid individual may submit evidence showing that all or part of the debt is not past due or not legally enforceable as provided in paragraph (a) of this section. Failure to submit the notification and evidence within 60 calendar days will result in referral of the overpayment to the Department of the Treasury, unless the overpaid individual, within this 60-day time period, has asked us to waive collection of the overpayment under section 1631(b)(1)(B) of the Act and we have not yet determined whether we can grant the waiver request. If the overpaid individual asks us to waive collection of the overpayment, we may ask that evidence to support the request be submitted to us.

(c) *Review of the Evidence.* After a timely submission of evidence by the overpaid individual, we will consider all available evidence related to the overpayment. We will make findings based on a review of the written record, unless we determine that the question of indebtedness cannot be resolved by a review of the documentary evidence.

§ 416.583 Findings by SSA.

(a) Following the review of the record, we will issue written findings which include supporting rationale for the findings. Issuance of these findings concerning whether the overpayment or part of the overpayment is past due and legally enforceable is the final Agency action with respect to the past-due status and enforceability of the overpayment. If we make a determination that a waiver request cannot be granted, we will issue a written notice of this determination in accordance with the regulations in subpart E of this part. Our referral of the overpayment to the Department of the Treasury will not be suspended under § 416.585 of this subpart pending any further administrative review of the waiver request that the individual may seek.

(b) Copies of the findings described in paragraph (a) of this section will be distributed to the overpaid individual and the overpaid individual's attorney or other representative, if any.

(c) If the findings referred to in paragraph (a) of this section affirm that all or part of the overpayment is past due and legally enforceable and, if waiver is requested and we determine that the request cannot be granted, we will refer the overpayment to the Department of the Treasury. However, no referral will be made if, based on our review of the overpayment, we reverse our prior finding that the overpayment is past due and legally enforceable or, upon consideration of a waiver request, we determine that waiver of our collection of the overpayment is appropriate.

§ 416.584 Review of our records related to the overpayment.

(a) *Notification by the overpaid individual.* An overpaid individual who intends to inspect or copy our records related to the overpayment as determined by us must notify us stating his or her intention to inspect or copy.

(b) *Our response.* In response to a notification by the overpaid individual as described in paragraph (a) of this section, we will notify the overpaid individual of the location and time when the overpaid individual may inspect or copy our records related to the overpayment. We may also, at our discretion, mail copies of the overpayment-related records to the overpaid individual.

§ 416.585 Suspension of offset.

If, within 60 days of the date of the notice described in § 416.581 of this subpart, the overpaid individual notifies us that he or she is exercising a right described in § 416.582(a) of this subpart and submits evidence pursuant to § 416.582(b) of this subpart or requests a waiver under § 416.550 of this subpart, we will suspend any notice to the Department of the Treasury until we have issued written findings that affirm that an overpayment is past due and legally enforceable and, if applicable, make a determination that a waiver request cannot be granted.

§ 416.586 Tax refund insufficient to cover amount of overpayment.

If a tax refund is insufficient to recover an overpayment in a given year, the case will remain with the Department of the Treasury for succeeding years, assuming that all criteria for certification are met at that time.

3. The authority citation for subpart N is revised to read as follows:

Authority: Secs. 702(a)(5), 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1383, and 1383b); 31 U.S.C. 3720A.

4. Section 416.1403 is amended by deleting the word ''and'' at the end of paragraph (a)(15), replacing the period at the end of paragraph (a)(16) with ''; and'', and adding paragraph (a)(17) to read as follows:

§ 416.1403 Administrative actions that are not initial determinations.

(a) * * *

(17) Findings on whether we can collect an overpayment by using the Federal income tax refund offset procedure. (See § 416.583).

* * * * *

[FR Doc. 97–16132 Filed 6–20–97; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. 97N–0217]

Request for Comments on Development of Options to Encourage Animal Drug Approvals for Minor Species and for Minor Uses

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments and suggestions relating to legislative and regulatory options to facilitate the approval of new animal

drugs intended for use in minor species or intended for minor uses. The agency is seeking comments and suggestions to assist its Center for Veterinary Medicine (CVM) in fulfilling its responsibility under the Animal Drug Availability Act of 1996 (the ADAA) to issue a report setting forth legislative and regulatory options to facilitate approvals of new animal drugs that fall into these two categories. Facilitating approvals for minor uses and minor species will bring about an increase in approvals of new animal drugs intended for these uses, which would be desirable to address the scarcity of approved, legally marketed new animal drugs intended for minor species or minor uses.

DATES: Written comments by September 8, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: George A. (Bert) Mitchell, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1761.

SUPPLEMENTARY INFORMATION:

I. Background

''Minor use'' of new animal drugs is defined in the Code of Federal Regulations at § 514.1(d)(1)(i) (21 CFR 514.1(d)(1)(i)) as ''the use of: (*a*) New animal drugs in minor animal species, or (*b*) new animal drugs in any animal species for the control of a disease that (*1*) occurs infrequently or (*2*) occurs in limited geographic areas.''

''Minor species'' are defined at § 514.1(d)(1)(ii) as ''animals other than cattle, horses, swine, chickens, turkeys, dogs, and cats. Sheep are a minor species with respect to effectiveness and animal safety data collection requirements; sheep are a major species with respect to human safety data collection requirements arising from the possible presence of drug residues in food.''

Because the markets are small for approved new animal drugs intended for minor species or for minor uses, there are often insufficient economic incentives to motivate sponsors to develop the data necessary to support approvals. Consequently, manufacturers have not, in many cases, been willing to fund research to obtain these data. Accordingly, only small numbers of new animal drugs intended for minor species or for minor uses have been approved and are legally marketed.

Because of the limited availability of approved new animal drugs intended for use in minor species or for minor uses, veterinarians, animal owners, and livestock producers have limited options for treatment of sick animals. In many cases, the available choices are to leave a sick animal untreated or to treat the animal with an unapproved drug. Even though it might appear that the absence of drug treatment would be safe for both the public and the environment, in the absence of approved therapies, there are increased public health hazards associated with the failure to treat sick animals. For example, the transmission of zoönotic disease is a significant public health risk associated with leaving animals untreated, as is the reduced wholesomeness of food associated with higher morbidity and mortality resulting from failure to treat. The shedding of disease-producing organisms by untreated animals into the environment also increases health risks to other animals and to humans.

Although FDA has attempted to encourage the submission of approvals for minor species and uses in various ways, the agency's efforts to promote such approvals have thus far met with only limited success.

In addition, FDA recently issued final regulations implementing the Animal Medicinal Drug Use Clarification Act of 1994 (the AMDUCA) (Pub. L. 103–396). The AMDUCA and the implementing regulations allow veterinarians, if they follow the conditions set forth in the regulations, to prescribe approved drugs for extralabel therapeutic use in animals. While the AMDUCA does give veterinarians more legal treatment options, the AMDUCA will not, and was not intended to, facilitate the approval of new animal drugs for minor species or minor uses.

II. The ADAA

On October 9, 1996, the President signed the ADAA (Pub. L. 104–250) into law. The primary purpose of the ADAA is to facilitate the approval and marketing of new animal drugs and medicated feeds by building ''needed flexibility'' into the animal drug review processes ''to enable more efficient approval and more expeditious marketing of safe and effective animal drugs'' (H. Rept. 104–823 at 8).

Section 2(f) of the ADAA directs the Secretary of Health and Human Services (the Secretary) to consider legislative and regulatory options for facilitating approval under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b) of new animal drugs intended for use in minor species or for minor uses. The ADAA further requires the Secretary to announce proposals for legislative or regulatory change to the approval process for new animal drugs intended for use in minor species or for minor uses within 18 months after the date of enactment (i.e., no later than April 9, 1998).

CVM plans to publish a notice of availability in the **Federal Register** and solicit comments on a revised guidance entitled ''Minor Use Guidance Document: A Guide to the Approval of Animal Drugs for Minor Uses and for Minor Species.'' CVM intends this revised guidance will be published as a Level 1 guidance document to facilitate the submission of new animal drug applications for drugs intended for minor uses and for minor species by clarifying how the agency believes that new animal drug approvals for minor species and for minor uses can be achieved, even as FDA develops the proposals required under the ADAA.

This notice requests comments from animal drug manufacturers, users of animal drugs, and interested groups and individuals so that the agency can fulfill this statutory mandate of the ADAA.

III. Agency Request for Comments

FDA is in the process of developing legislative and regulatory options for encouraging approvals of new animal drugs for use in minor species and for minor uses. As part of this process, the agency believes that it would be helpful to obtain comments and additional information on particular issues, as well as additional suggestions of legislative or regulatory options. FDA would find especially helpful comments that address target animal safety, food safety, effectiveness, labeling, manufacturing, environmental impact, and other concerns related to the agency's statutory responsibilities.

Accordingly, FDA is specifically requesting comments and information on the questions and subjects below. This list is not all-inclusive, however, and is not intended to limit the range of options available for public comment. The agency asks that comments be as detailed as possible, with explanations and information to assist FDA in evaluating whether the approaches will effectuate the purposes of the ADAA: That products be safe and effective, accurately labeled, consistently produced, and, most critically, whether the result will be larger numbers of approved new animal drugs for use in minor species or for minor uses.

FDA does not intend anyone to read this list as any indication of the agency's position on a particular approach or a determination that the agency has the resources to implement such an approach.

A. Scope

The agency seeks comments on the criteria found at § 514.1(d)(1) for the determination of a minor species or a minor use.

B. Creating Additional Statutory Authority

Should there be different standards for target animal safety and effectiveness of new animal drugs intended for use in minor species or for minor uses? Should there be different standards for human food safety for new animal drugs intended for minor species and for minor uses? If so, what should those standards be? Should the standards be the same for all minor species or uses? Why? Should products be labeled to reflect the use of different standards? If not, why not? If the act were amended to permit FDA to approve new animal drugs for a minor species or minor use under different standards, how would appropriate doses be determined and how would residue depletion and withdrawal times for food animals be determined?

On the human drug side, certain critical drugs for life-threatening and serious diseases are approved though an accelerated approval process in which followup studies are required to confirm approval (see 21 CFR part 314, subpart H). Similarly, section 522 of the act (21 U.S.C. 360l) requires and authorizes the agency to require postmarket surveillance of certain devices to protect the public health or provide safety and effectiveness data. Would sponsors and users accept conditional approvals and postmarket surveillance as a tradeoff for requiring less in the way of premarket target animal safety and effectiveness studies for new animal drugs for minor species or minor uses? Should a drug approved under such a mechanism bear labeling that reflects its conditional status?

Should the act be amended to allow FDA to accept foreign reviews or approvals of new animal drugs for minor species or for minor uses? How should Congress or FDA determine whether the reviews or approvals of a particular country or countries are acceptable as a basis for approval of uses for minor species or for minor uses.

Should the current statutory standard for new animal drug approval for drugs intended for minor species or minor uses or any alternative standard be implemented through a primary review process external to the agency? If so, how might this process be administered? Who should pay for the external reviews?

Could determinations of animal safety and effectiveness by expert panels or compendia be used to support drug approvals for minor species and minor uses? If so, what information would serve as the basis for such determinations? Should the determinations of these panels or other information be used to issue monographs or similar standards? Who would draft monographs or similar standards and why?

C. Administrative and Regulatory Changes

Should there be different standards for manufacturing of drugs for minor species or minor uses? If so, what should those standards be? Should products be labeled to reflect the use of different manufacturing standards?

Would a strategy similar to that used by the agency to facilitate drug approvals for some aquatic species be successful if extended to other minor species? That strategy includes coordination of investigational new animal drug (INAD) information collected or generated by end users. It also includes a centrally-organized and CVM-operated field education program directed at end users as potential INAD sponsors. In which species/uses would such an approach work or not work? Why?

D. Creating Incentives

Would economic incentives, such as tax breaks, grants, and periods of market or label exclusivity, encourage the pursuit of approvals or supplemental approvals for labeling modifications for minor species or minor uses? If so, what kinds of incentives would be most effective? Would different kinds of incentives be appropriate for different classes of new animal drugs, such as drugs for hobbyist-owned tropical fish as contrasted with production drugs for fish intended for human consumption?

What incentives would encourage sponsors to pursue approval of a drug for a minor species or for a minor use using data in public master files (PMF's)? Are there concerns about data in PMF's that make new animal drug sponsors reluctant to rely on such data? What are those concerns? How could they be addressed?

If producer groups or other organizations were willing to conduct or otherwise fund studies to demonstrate safety and efficacy for new animal drug approvals for minor species or minor uses, would sponsors be willing to use the data from the studies to support approvals and new or revised labeling? If not, why not?

Should a program similar to the U.S. Department of Agriculture's National Research Support Program #7 (NRSP–7), which currently funds studies for minor use therapeutic uses for food- and fiber-producing animals, be developed for wildlife and zoo animals and/or for production uses? Should the NRSP–7 program be expanded to cover such uses?

Could and should philanthropic, public interest, or other not-for-profit organizations be encouraged to fund research for the development of new animal drugs intended for use in minor species or for minor uses? If so, how, and by whom?

Are there mechanisms other than the new animal drug approval process and extralabel uses of animal and human drugs under the AMDUCA that could enhance drug availability for minor species and for minor uses?

E. Extending Existing Legal Authority

Would legislation be desirable to extend the AMDUCA to permit extralabel use of: (1) Medicated feeds or (2) reproductive hormones and implants? What are the pros and cons of approval versus extralabel use under the AMDUCA?

IV. Comments

Interested persons may, on or before September 8, 1997, submit to the Dockets Management Branch (address above) written comments regarding this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 12, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–16340 Filed 6–18–97; 1:40 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 808

[Docket No. 96N–0249]

Applications for Exemption From Preemption of State and Local Requirements Pertaining to the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents

AGENCY: Food and Drug Administration, HHS.