second test, we will consider the following factors:

(1) Would the disclosure further a commercial interest of the requester, or of someone on whose behalf the requester is acting? ''Commercial interests'' include interests relating to business, trade, and profit. Not only profit-making corporations have commercial interests—so do nonprofit corporations, individuals, unions, and other associations. The interest of a representative of the news media in using the information for news dissemination purposes will not be considered a commercial interest.

(2) If disclosure would further a commercial interest of the requester, would that effect outweigh the advancement of the public interest defined in paragraph (b) of this section? Which effect is primary?

(d) *Deciding between waiver and reduction.* If the disclosure passes both tests, we will normally waive fees. However, in some cases we may decide only to reduce the fees. For example, we may do this when disclosure of some but not all of the requested records passes the tests.

(e) *Procedure for requesting a waiver or reduction.* You must make your request for a waiver or reduction at the same time you make your request for records. You should explain why you believe a waiver or reduction is proper under the analysis in paragraphs (a) through (d) of this section. Only FOI Officers may make the decision whether to waive, or reduce, the fees. If we do not completely grant your request for a waiver or reduction, the denial letter will designate a review official. You may appeal the denial to that official. In your appeal letter, you should discuss whatever reasons are given in our denial letter. The process prescribed in § 402.190 of this part will also apply to these appeals.

§ 402.190 Officials who may deny a request for records under FOIA.

Only the Director, Office of Disclosure Policy, SSA, or her or his designee is authorized to deny a written request to obtain, inspect, or copy any social security record.

§ 402.195 How a request is denied.

(a) *Oral requests.* If we cannot comply with your oral request because the Director of the Office of Disclosure Policy (or designee) has not previously made a determination to release the record you want, we will tell you that fact. If you still wish to pursue your request, you must put your request in writing.

(b) *Written requests.* If you make a written request and the information or record you requested will not be released, we will send you an official denial in writing. We will explain why the request was denied (for example, the reasons why the requested document is subject to one or more clearly described exemptions), will include the name and title or position of the person who made the decision, and what your appeal rights are.

(c) *Unproductive searches.* We make a diligent search for records to satisfy your request. Nevertheless, we may not be able always to find the records you want using the information you provided, or they may not exist. If we advise you that we have been unable to find the records despite a diligent search, this does not constitute a denial of your request.

§ 402.200 How to appeal a decision denying all or part of a request.

(a) *How to appeal.* If all or part of your written request was denied, you may request that the Commissioner of Social Security, 6401 Security Boulevard, Baltimore, MD 21235 review that determination. Your request for review:

(1) Must be in writing;

(2) Must be mailed within 30 days after you received notification that all or part of your request was denied or, if later, 30 days after you received materials in partial compliance with your request; and

(3) May include additional information or evidence to support your request.

(b) *How the review is made.* After reviewing the prior decision and after considering anything else you have submitted, the Commissioner or his or her designee will affirm or revise all or part of the prior decision. The Commissioner (or a designee) will affirm a denial only after consulting with the appropriate SSA official(s), including legal counsel. The decision must be made within 20 working days after your appeal is received. The Commissioner or a designee may extend this time limit up to 10 additional working days if one of the situations in § 402.140(a) exists, provided that, if a prior extension was used to process this request, the sum of the extensions may not exceed 10 working days. You will be notified in writing of any extension, the reason for the extension, and the date by which your appeal will be decided.

(c) *How you are notified of the Commissioner's decision.* The Commissioner or a designee will send you a written notice of the decision explaining the basis of the decision (for example, the reasons why an exemption applies) which will include the name and title or position of the person who made the decision. The notice will tell you that if any part of your request remains unsatisfied, you have the right to seek court review.

§ 402.205 U.S. District Court action.

If the Commissioner or a designee, upon review, affirms the denial of your request for records, in whole or in part, you may ask a U.S. District Court to review that denial. See 5 U.S.C. 552(a)(4)(B). If we fail to act on your request for a record or for review of a denial of such a request within the time limits in § 402.140(a) or in § 402.190(b), you may ask a U.S. District Court to treat this as if the Commissioner had denied your request.

PART 422—ORGANIZATION AND PROCEDURES

Subpart E of Part 422—[Removed]

3. Under the authority of section 106(b) of Pub. L. 103–296, Social Security Independence and Program Improvements Act of 1994, subpart E of part 422, is removed and reserved.

[FR Doc. 97–1271 Filed 1–28–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Animal Drugs, Feeds, and Related Products; Tripelennamine Hydrochloride Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to more clearly reflect the currently approved conditions of use of a new animal drug application (NADA) held by Solvay Animal Health, Inc. The NADA provides for use of tripelennamine hydrochloride injection for antihistaminic therapy in horses and cattle. The amendment provides for tolerances for drug residues in edible cattle tissues and in milk and the corresponding drug withdrawal and milk discard periods. When the NADA was reviewed under the National Academy of Sciences/National Research Council Drug Study Implementation Program and the results of the review finalized in 1983, this information was inadvertently omitted from the regulations.

EFFECTIVE DATE: January 29, 1997.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

SUPPLEMENTARY INFORMATION: Solvay Animal Health, Inc., 1201 Northland Dr., Mendota Heights, MN 55120, is sponsor of NADA 6–417. The application provides for intravenous or intramuscular use of tripelennamine hydrochloride injection in cattle and intramuscular use in horses for treating conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease. FDA is amending the regulations to reflect additional limitations currently in the approved drug labeling and publishing tolerances for drug residues in cattle tissues and in milk. The product is for veterinary prescription use only. The regulations are amended in 21 CFR 522.2615(c) to reflect the required withdrawal period and milk discard time and in 21 CFR part 556 to reflect the tolerance for residues in cattle tissues and in milk.

List of Subjects

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 522 and 556 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.2615 is amended by redesignating paragraph (c) as paragraph (d), adding new paragraph (c), and revising newly redesignated paragraph (d)(3) to read as follows:

§ 522.2615 Tripelennamine hydrochloride injection.

* * * * *

(c) *Related tolerances.* See § 556.741 of this chapter.

(d) * * *

(3) *Limitations.* Do not use in horses intended for food purposes. Treated cattle must not be slaughtered for food during treatment and for 4 days following the last treatment. Milk that has been taken during treatment and for 24 hours (two milkings) after the last treatment must not be used for food. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: Secs. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

4. New § 556.741 is added to read as follows:

§ 556.741 Tripelennamine.

A tolerance of 200 parts per billion (ppb) is established for residues of tripelennamine in uncooked edible tissues of cattle and 20 ppb in milk.

Dated: January 7, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–2140 Filed 1–28–97; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Parts 812 and 813

[Docket No. 91N–0292]

Investigational Device Exemptions; Intraocular Lenses

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to remove the regulations on investigational device exemptions (IDE's) for intraocular lenses (IOL's). An IOL is an implant intended to surgically replace the natural lens of the human eye. FDA believes it is no longer necessary to maintain particularized regulations on IOL investigations because approved IOL's are now widely available and investigations of IOL's can be conducted under the investigational device regulations applicable to medical devices generally. This action is intended to eliminate confusion within the clinical research community and to provide uniformity to investigational device studies.

EFFECTIVE DATE: March 31, 1997.

FOR FURTHER INFORMATION CONTACT: Joanne R. Less, Center for Devices and Radiological Health (HFZ–403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has two regulations on investigational use of medical devices. Part 812 (21 CFR part 812) covers investigational devices generally, and part 813 (21 CFR part 813) applies only to IOL's. The existence of a separate regulation for investigational use of IOL's is due to provisions of the Medical Device Amendments of 1976 (1976 amendments) (Pub. L. 94–295) that addressed IOL's and to particular issues surrounding IOL products at that time.

FDA has determined that maintaining two closely related sets of investigational device regulations is no longer necessary. Thus, FDA has reexamined the need to retain part 813, and the agency has concluded that maintaining a regulatory distinction between IOL studies and studies of other medical devices is no longer justified. Therefore, in order to eliminate confusion within the clinical research community and to provide uniformity to investigational device studies, FDA is removing the IOL regulations in their entirety and removing § 812.2(c)(8) to exempt IOL's from part 812 when the IOL's are the subject of an approved premarket approval application under section 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e).

In the Federal Register of October 6, 1993 (58 FR 52142), FDA published a proposed rule to remove the regulations on IOL's. In that same issue, FDA also proposed procedures for disqualification of clinical investigators for inclusion in the current general investigational device regulations. FDA provided an opportunity for interested persons to submit comments on the proposed removal of the IOL regulations by December 6, 1993. Subsequently, in the Federal Register of December 6, 1993 (58 FR 64209), FDA extended the comment period to January 5, 1994. In a future issue of the Federal Register, FDA will issue final procedures for disqualification of clinical investigators as part of the current general investigational device regulations in part 812.

II. Comments

The agency received two comments in response to the proposal of October 6, 1993, with respect to IOL's. One of the comments was submitted by a trade association. The other comment was submitted by a manufacturer. A