

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 tripeleonnamine 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 Tripeleonnamine 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 Tripeleonnamine.

A tolerance of 200 parts per billion (ppb) is established for residues of tripeleonnamine 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]

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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

summary of the comments and the agency's response to them is provided below:

(1) One comment concurred with FDA's proposal to remove the separate regulation on IDE's for IOL's contained in part 813. However, because part 813 contains some provisions that are not reflected in part 812, the comment suggested that FDA identify what, if any, additional information FDA would require IDE submissions for IOL's to include.

Under the final rule, any requirements unique to part 813 would no longer apply. The content of IDE submissions for IOL's only need to include information required in IDE submissions for investigational devices generally. For example, with respect to institutional review boards (IRB's) (referred to in part 813 as institutional review committees), the sponsor will only be required to submit the information required by § 812.20(b)(6) and not that required by § 813.20(b)(7).

(2) Both comments recommended that FDA provide in the final rule a mechanism for IOL clinical investigations that are in progress before the final rule becomes effective to continue under part 813 until those investigations are completed or terminated. One comment also noted that, because investigators have not signed statements agreeing to conform to part 812, application of the requirements of part 812 to ongoing IOL studies would create confusion and add to the cost of the ongoing studies.

FDA does not believe that the continuation of part 813 requirements for existing studies is necessary. The differences between parts 812 and 813 are relatively minor. Investigators who are in compliance with part 813 will also generally be in compliance with part 812. Sponsors may seek a waiver under part 812, if there are any difficulties as a result of the change from part 813 to part 812. FDA, however does not anticipate any difficulties.

(3) Both comments emphasized that part 812 has certain requirements that are not included in part 813. For example, § 812.150(b)(4) requires the sponsor to submit a semi-annual investigator list to FDA; § 812.150(b)(5) requires the sponsor to submit annual progress reports to all reviewing IRB's; and § 812.150(b)(8) requires the sponsor to submit to FDA a copy of any report by an investigator under § 812.150(a)(5) within 5 working days of receipt. Both comments requested that these additional rules not be imposed on IOL studies conducted under part 812.

FDA does not believe that maintaining this type of distinction is

necessary. Experience over the past 15 years has shown that the requirements of part 812 are reasonable and that sponsors of investigations under part 812 have not had undue difficulty complying with these provisions. As noted in section II (2) of this document, part 812 contains a waiver provision that can be utilized on a case-by-case basis, if needed.

(4) One comment asked how IRB's would be notified of the new rule.

FDA will send letters to sponsors of all active IOL IDE investigations, and the agency will request that sponsors inform investigators and IRB's of the change. Additionally, FDA will publicize the new rule at the regional IRB meetings and at other appropriate forums.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) 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.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule removes existing regulations on investigational studies of IOL's and requires such investigations to be conducted under the IDE regulations in part 812 applicable to medical devices generally, the agency certifies that the final rule will not impose any significant new burdens on sponsors and investigators of IOL's and will not have a significant economic impact on a substantial number of small entities. Therefore,

under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 813

Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, chapter I of title 21 of the Code of Federal Regulations is amended in 21 CFR parts 812 and 813 as follows:

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

1. The authority citation for 21 CFR part 812 continues to read as follows:

Authority: Secs. 301, 501, 502, 503, 505, 506, 507, 510, 513-516, 518-520, 701, 702, 704, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 353, 355, 356, 357, 360, 360c-360f, 360h-360j, 371, 372, 374, 379e, 381); secs. 215, 301, 351, 354-360F of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263b-263n).

§ 812.2 [Amended]

2. Section 812.2 *Applicability* is amended by removing paragraph (c)(8).

PART 813—INVESTIGATIONAL EXEMPTIONS FOR INTRAOCULAR LENSES

Part 813 [Removed and Reserved]

3. Part 813, consisting of §§ 813.1 through 813.170, is removed and reserved.

Dated: January 22, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97-2169 Filed 1-28-97; 8:45 am]

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DEPARTMENT OF EDUCATION

34 CFR Part 75

RIN 1880-AA61

Direct Grant Programs

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the Department's regulations on direct grant programs to expand the basis for selecting applications for new grants to include a recipient's previous