§ 500.49 [Removed]

4. Section 500.49 *Chlorofluorocarbon propellants* is removed.

PART 505—[REMOVED]

5. Part 505 is removed.

PART 507—[REMOVED]

6. Part 507 is removed.

PART 508—[REMOVED]

7. Part 508 is removed.

PART 510—NEW ANIMAL DRUGS

8. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

§ 510.120 [Removed]

9. Section 510.120 *Suspension of approval of new-drug applications for certain diethylstilbestrol and diethylstilbestrol-containing drugs* is removed.

§ 510.200 [Removed]

10. Subpart C, consisting of § 510.200, is removed and reserved.

§ 510.310 [Removed]

11. Section 510.310 *Records and reports for new animal drugs approved before June 20, 1963* is removed.

§ 510.413 [Removed]

12. Section 510.413 *Chloroform used as an ingredient (active or inactive) in animal drug products* is removed.

PART 570—FOOD ADDITIVES

13. The authority citation for 21 CFR part 570 continues to read as follows:

Authority: Secs. 201, 401, 402, 408, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 346a, 348, 371).

§ 570.22 [Removed]

14. Section 570.22 *Safety factors to be considered* is removed.

Dated: July 3, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–18234 Filed 7–18–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Gonadorelin Diacetate Tetrahydrate Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Intervet, Inc. The ANADA provides for intramuscular and intravenous use of a sterile injectable solution of gonadorelin diacetate tetrahydrate for treating ovarian cysts in female dairy cattle of breeding age.

EFFECTIVE DATE: July 19, 1996.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Intervet, Inc., 405 State St., P.O. Box 318, Millsboro, DE 19966–0318, filed ANADA 200–134, which provides for intramuscular and intravenous use of Fertagyl® (gonadorelin diacetate tetrahydrate injection) for treatment of ovarian cysts in female dairy cattle of breeding age.

Approval of ANADA 200–134 is as a generic copy of Rhone Merieux's NADA 98–379 for Cystorelin® (gonadorelin diacetate tetrahydrate injection). The ANADA is approved as of June 17, 1996, and the regulations are amended by revising 21 CFR 522.1078(b) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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.

List of Subjects in 21 CFR Part 522

Animal drugs.

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 part 522 is 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).

§ 522.1078 [Amended]

2. Section 522.1078 *Gonadorelin diacetate tetrahydrate injection* is amended in paragraph (b) by removing ''No. 050604'' and adding in its place ''Nos. 050604 and 057926''.

Dated: July 11, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–18350 Filed 7–18–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 801

[Docket No. 95N–310R]

RIN 0910–AA54

Revocation of Certain Device Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to remove certain device regulations that are obsolete or no longer necessary to achieve public health goals. These regulations have been identified for revocation as the result of a page-by-page review of the agency's regulations in response to the administration's ''Reinventing Government'' initiative, which seeks to streamline Government and ease the burden on regulated industry and consumers.

EFFECTIVE DATE: August 19, 1996.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Background

On March 4, 1995, President Clinton announced plans for the reform of the Federal regulatory system as part of the administration's ''Reinventing Government'' initiative. In his March 4, 1995, directive, entitled ''Regulatory Reinvention Initiative,''the President ordered all Federal agencies to conduct a page-by-page review of all of their regulations and to ''eliminate or revise

those that are outdated or otherwise in need of reform.'' The first results of FDA's efforts in implementing the President's plan were published in the Federal Register of October 13, 1995 (60 FR 53480). That document identified the regulations that FDA was proposing to eliminate, and the Centers within the agency responsible for those regulations.

The agency received no comments on the proposed revocation of regulations administered by the Center for Devices and Radiological Health (CDRH). This final rule will finalize the proposed revocation of the following regulations administered by CDRH:

II. Section-by-Section Analysis

1. Section 801.403 *Specific medical devices; recommended warning and caution statements* (21 CFR 801.403). This regulation recommends certain warning and caution statements for: Denture reliners, pads, and cushions; denture repair kits; infrared generators (including heating pads); insulin syringes; mechanical massagers and vibrators; steam or turkish baths; and ultraviolet generators. This section does not contain specific requirements and will therefore be removed from the Code of Federal Regulations (CFR).

2. Section 801.408 *Pessaries for intracervical and intrauterine use* (21 CFR 801.408). This section contains information that can be more appropriately given as statements of policy and will therefore be removed from the CFR.

3. Section 801.427 *Professional and patient labeling for intrauterine contraceptive devices* (21 CFR 801.427). This regulation is no longer necessary because these devices are no longer being marketed. If any intrauterine contraceptive devices are approved in the future, the labeling will be approved during the premarket approval process. This regulation will therefore be removed from the CFR.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). 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 this final rule removes unnecessary labeling regulations, the agency certifies that the rule 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.

IV. Environmental Impact

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

List of Subjects in 21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 801 is amended as follows:

PART 801—LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 507, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 357, 360i, 360j, 371, 374).

§ 801.403 [Removed]

2. Section 801.403 *Specific medical devices; recommended warning and caution statements* is removed.

§ 801.408 [Removed]

3. Section 801.408 *Pessaries for intracervical and intrauterine use* is removed.

§ 801.427 [Removed]

4. Section 801.427 *Professional and patient labeling for intrauterine contraceptive devices* is removed.

Dated: July 11, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–18233 Filed 7–18–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[T.D. 8128]

Miscellaneous Provisions Relating to the Tax Treatment of Partnership Items; Procedure and Administration; OMB Control Numbers; Correction

AGENCY: Internal Revenue Service, Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to temporary regulations (T.D. 8128), which were published in the Federal Register on Thursday, March 5, 1987 (52 FR 6779) relating to certain rules for the tax treatment of partnership items.

EFFECTIVE DATE: March 5, 1987.

FOR FURTHER INFORMATION CONTACT: D. Lindsay Russell (202) 622–3050, (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations that are the subject of this correction is under sections 6221 thru 6233 of the Internal Revenue Code.

Need for Correction

As published, the temporary regulations (T.D. 8128) contains an error which may prove to be misleading and is in need of clarification.

List of Subjects in 26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Accordingly, 26 CFR part 301 is corrected by making the following correcting amendment:

PART 301—PROCEDURE AND ADMINISTRATION

Paragraph 1. The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

§ 301.6231(a)(7)–1T [Correctly redesignated from § 301.6231(a)(7)–1]

Par. 2. Section 301.6231(a)(7)–1 is redesignated as § 301.6231(a)(7)–1T.

Michael L. Slaughter,

Acting Chief, Regulations Unit, Assistant Chief Counsel (Corporate).

[FR Doc. 96–18139 Filed 7–18–96; 8:45 am]

BILLING CODE 4830–01–P