

FR 41348), FDA published a final rule that amended the labeling control provisions in the CGMP regulations. The final rule defined the term "gang-printed labeling," specified conditions for the use of gang-printed or cut labeling, exempted manufacturers that employ certain automated inspection systems from labeling reconciliation requirements, and made other revisions intended to reduce the frequency of drug product mislabeling and associated drug product recalls. One of the three special control options for cut labeling is the use of "appropriate electronic or electromechanical equipment to conduct a 100-percent examination for correct labeling during or after completion of finishing operations" (§ 211.122(g)(2)).

In response to two citizen petitions requesting certain amendments to § 211.122(g) as it applies to cut labeling, a stay of the effective date, and reopening of the administrative record, FDA, in the Federal Register of August 2, 1994 (59 FR 39255), granted a partial extension of the compliance date for certain provisions of § 211.122(g) to August 3, 1995, and a limited reopening of the administrative record. In the Federal Register of April 28, 1995 (60 FR 20897), FDA granted a further partial extension of the compliance date to August 2, 1996.

FDA extended the compliance date to provide industry with additional time to comply with certain provisions of the final rule. FDA found that additional time was needed to locate, install, and validate scanning equipment and other necessary equipment to orient items properly for bar code scanning because there was a shortage of contract engineering personnel employed by some drug manufacturers to evaluate, select, purchase, install, qualify, and validate labeling verification systems.

FDA reopened the administrative record to receive additional comments on the application of § 211.122(g) to items of labeling (other than the immediate container label) as defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(m)), and whether § 211.122(g) expanded the proposed scope of the provision from immediate container labels to all drug product labeling.

FDA has held a number of meetings with representatives of the labeling industry and others to determine control options available through current technology and to evaluate this information in light of comments received during the extended comment period. To assess this information adequately, provide industry with adequate time to comply fully with a

final regulation, and provide additional time for FDA to consider any revisions to the final rule, the agency is extending to August 1, 1997, the compliance date for § 211.122(g) as it applies to items of labeling other than the immediate container label.

FDA's determination as to whether § 211.122(g) will be retained as currently codified or whether it will be revised will be published in a future issue of the Federal Register. The compliance date for the remainder of § 211.122, including § 211.122(g) as it applies to immediate container labels, was August 3, 1994. The agency emphasizes that, under 21 CFR 211.125, a waiver of labeling reconciliation is conditioned on a 100-percent examination for correct labeling performed in accordance with § 211.122(g)(2).

Dated: July 11, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96-18285 Filed 7-18-96; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Parts 500, 505, 507, 508, 510, and 570

[Docket No. 95N-310V]

Revocation of Certain Animal Food and Drug Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking certain regulations regarding animal food and animal drugs 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. This regulatory review is in response to the administration's "Reinventing Government" initiative which seeks to streamline Government to ease the burden on regulated industry and consumers. These regulations are being consolidated in order to respond to "Reinventing Government."

EFFECTIVE DATE: August 19, 1996.

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: Kristi O. Smedley, Center for Veterinary Medicine (HFV-238), Food and Drug

Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1737.

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 directive, 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." In the Federal Register of October 13, 1995 (60 FR 53480), FDA provided its initial efforts in implementing the President's plan. The proposed rule announced regulations that FDA intended to eliminate based on the page-by-page review.

The agency received no comments regarding their intention to eliminate any of the regulations that cover animal food or animal drug regulations. Therefore the agency is removing the following regulations:

1. Section 500.49 *Chlorofluorocarbon propellants* (21 CFR 500.49). This section prohibits the use of chlorofluorocarbons as propellants in self-pressurized containers in animal drugs. Chlorofluorocarbons are prohibited by the Clean Air Act Amendments of 1990 (42 U.S.C. 7671) and can no longer be marketed for this use. This section is unnecessary because coverage in § 2.125 (21 CFR 2.125) of this prohibition is sufficient.

2. Section 505.3 *Warnings on animal drugs intended for administration to diseased animals* (21 CFR 505.3). This section states that no warning or caution statements recommended for use in the labeling of animal drugs intended for administration to diseased animals shall be construed to suggest or imply that a product of diseased animals is suitable for food use. This provision cautions against misuse of language in § 505.20 (21 CFR 505.20) which is now being withdrawn and is, therefore, unnecessary.

3. Section 505.20 *Recommended animal drug warning and caution statements*. This section provides recommended animal drug warning and caution statements for specific drugs. The statements provided are voluntary label statements that do not contain requirements and need not appear in the CFR.

4. Part 507—Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (21 CFR part 507). This part contains the criteria that apply in determining whether the facilities, methods, practices, and

controls used by the commercial processor in the manufacture, processing, and packing of low-acid foods for animals in hermetically sealed containers are operated or administered in a manner adequate to protect the public health. Part 507 is identical to part 113 (21 CFR part 113), which applies to human foods. Therefore, the agency is removing part 507, and adding a new § 500.23 to state that the provisions in part 113 apply to animal foods.

5. Part 508—Emergency Permit Control (21 CFR part 508) covers the requirements and issuance of emergency control permits for the manufacturer or packer of thermally processed low-acid foods packaged in hermetically sealed containers. Part 508 is identical to part 108 (21 CFR part 108), which applies to human foods. Therefore, the agency is removing part 508, and adding a new § 500.24 to state that the provisions in part 108 apply to food intended for animals.

6. Section 510.120 *Suspension of approval of new-drug applications for certain diethylstilbestrol and diethylstilbestrol-containing drugs* (21 CFR 510.120). This section provides the suspension of approval of the seven listed diethylstilbestrol (DES)-containing animal drug products. There are no approved new animal drug applications for DES-containing products. This regulation is obsolete and should be deleted.

7. Section 510.200 *Export of new animal drug* (21 CFR 510.200). This section states that to export a new animal drug the product must comply with regulations issued under section 512 of the act (21 U.S.C. 360b). This provision has been superseded by changes in the act (see 21 U.S.C. 381).

8. Section 510.310 *Records and reports for new animal drugs approved before June 20, 1963* (21 CFR 510.310). This section sets out separate requirements for recordkeeping and reporting to the agency for drugs approved prior to June 20, 1963. These requirements are outdated and inaccurate. The agency believes it is appropriate to apply the current recordkeeping and reporting requirements to drugs that were approved before 1963.

9. Section 510.413 *Chloroform used as an ingredient (active or inactive) in animal drug products* (21 CFR 510.413). This section prohibits the use of chloroform as an ingredient in animal drugs and provides certain requirements for products that contain chloroform that must be met by October 3, 1977. Chloroform is no longer used as an ingredient in any animal drug

formulations. Drug formulation is reviewed by the manufacturing chemists in FDA's Center for Veterinary Medicine (CVM), and this regulation is no longer necessary.

10. Section 570.22 *Safety factors to be considered* (21 CFR 570.22). This section sets out a proposed safety factor to be used by CVM scientists when there is not justification of a different safety factor. The safety factors provided in the regulations are scientifically obsolete for food additives intended for animals and are best handled within the review process.

II. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (Pub. L. 96-354), and Pub. L. 104-121. 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 deletions have no compliance costs and do not result in any new requirements, the agency certifies that the final 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.

Pub. L. 104-121 provides for a major rule is to be effective 60 days after date of publication in the Federal Register or 60 days after submission of the rule to Congress for review, whichever is later. This rule is not a major rule for purposes of Pub. L. 104-121. Therefore, this rule is effective 30 days after date of publication.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(9) 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

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Polychlorinated biphenyls (PCB's).

21 CFR Part 505

Animal drugs, Labeling, Over-the-counter drugs.

21 CFR Part 507

Animal foods, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 508

Animal foods.

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 570

Animal feeds, Animal foods, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 500, 505, 507, 508, 510, and 570 are amended as follows:

PART 500—GENERAL

1. The authority citation for 21 CFR part 500 continues to read as follows:

Authority: Secs. 201, 301, 402, 403, 409, 501, 502, 503, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371).

2. Section 500.23 is added to subpart B to read as follows:

§ 500.23 Thermally processed low-acid foods packaged in hermetically sealed containers.

The provisions of part 113 of this chapter shall apply to the manufacture, processing or packing of low-acid foods in hermetically sealed containers, and intended for use as food for animals.

3. Section 500.24 is added to subpart B to read as follows:

§ 500.24 Emergency permit control.

The provisions of part 108 of this chapter shall apply to the issuance of emergency control permits for the manufacturer or packer of thermally processed low-acid foods packaged in hermetically sealed containers, and intended for use as food for animals.

§ 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

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 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

21 CFR Part 522**Implantation or Injectable Dosage Form New Animal Drugs; Gonadorelin Diacetate Tetrahydrate Injection**

AGENCY: Food and Drug Administration, HHS.