easier for sponsors. No comments were received on the proposed rule.

II. Conclusion

Because the agency has determined that the underlying rationale in support of the amendment remains sound and because no comments or other information were received suggesting any modification, the revisions set forth in the proposed rule have not been modified in the final rule. Accordingly, the final rule deletes the specific requirement that required a sponsor to conduct oral, chronic, dose-response studies.

As stated in the proposal, this revision is consistent with the goals of the President's National Performance Review. The agency's actions are part of its continuing effort to achieve the objectives set forth in that initiative, which is intended to provide a comprehensive review of all rules in order to identify those that are obsolete and burdensome and to delete or revise them.

III. Environmental Impact

FDA has carefully considered the potential environmental effects of this action and has determined that this action is categorically excluded under 21 CFR 25.30(h). This action revises the requirements for testing the carcinogenicity of compounds used for food-producing animals, but will not cause an increase in the existing level of use or cause a change in the intended uses of the product or its substitutes. 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, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). 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, and distributive impacts and equity). The Regulatory Flexibility Act requires agencies to examine the economic impact of a rule on small entities. The Unfunded Mandates Reform Act requires agencies to prepare an assessment of anticipated costs and benefits before enacting any rule that may result in an expenditure in any one year by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation).

This amendment to the regulations setting forth the requirements for the carcinogenicity testing of compounds used in food-producing animals will eliminate the specific requirement that a sponsor must conduct oral, chronic, dose-response studies, giving the agency and sponsors greater flexibility in choosing the types of studies used for testing the carcinogenicity of compounds used in food-producing animals. The resultant expanded flexibility will make it easier and less costly for sponsors to complete required testing.

FDA concludes that this final rule is consistent with the principles set forth in the Executive order and in these two statutes. In addition, the agency has determined that this rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. Because the final rule does not impose a mandate that results in an expenditure of $100 million or more by State, local, and tribal governments in the aggregate, or by the private sector in any one year, a written statement and economic analysis are not required as prescribed under section 202(a) of the Unfunded Mandates Reform Act of 1995.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the rule will clarify FDA policy and simplify the process for submitting certain applications, 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.

V. Paperwork Reduction Act of 1995

FDA has determined that this rule contains no collection of information requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

VI. Federalism

FDA has analyzed the final rule in accordance with the principles set forth in Executive Order 12612 and has determined that this final rule does not warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 500

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 500 is amended as follows:

PART 500—GENERAL

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

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371.

§ 500.80 [Amended]

2. Section 500.80 *Scope of this subpart* is amended in paragraph (b) in the second sentence by removing the phrase ''must be oral, chronic, dose-response studies and''.

Dated: December 17, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–33483 Filed 12–22–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation and Injectable Dosage Form New Animal Drugs; Imidocarb Dipropionate

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 a new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The NADA provides for subcutaneous or intramuscular use of imidocarb dipropionate solution for dogs for treatment of babesiosis.

EFFECTIVE DATE: December 23, 1997

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1618.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, has filed NADA 141–071 Imizol® (imidocarb dipropionate) solution for subcutaneous or intramuscular use for treatment of dogs with clinical signs of babesiosis and/or demonstrated *Babesia* organisms in the blood. The drug is limited to use by or on the order of a licensed veterinarian. The NADA is approved as of November 7, 1997, and the regulations are amended by adding new

21 CFR 522.1156 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act, this approval for use in nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning November 7, 1997, because the application contains substantial evidence of the effectiveness of the drug involved and any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(a)(1) 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: 21 U.S.C. 360b.

2. New § 522.1156 is added to read as follows:

§ 522.1156 Imidocarb dipropionate solution.

(a) *Specifications*. Each milliliter of injectable solution contains 120 milligrams of imidocarb.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 6.6 milligrams imidocarb per kilogram (3 milligrams per pound) of body weight.

(ii) *Indications for use*. Treatment of clinical signs of babesiosis and/or demonstrated *Babesia* organisms in the blood.

(iii) *Limitations*. Use subcutaneously or intramuscularly. Not for intravenous use. Repeat the dose after 2 weeks for a total of two treatments. Imidocarb is a cholinesterase inhibitor. Do not use simultaneously with or a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: December 15, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–33486 Filed 12–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Salinomycin, Bacitracin Zinc, and Roxarsone

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 two abbreviated new animal drug applications (ANADA's) filed by Alpharma Inc. The ANADA's provide for using approved salinomycin, bacitracin zinc, and roxarsone Type A medicated articles to make Type C medicated broiler chicken feeds used for prevention of coccidiosis, increased rate of weight gain, and improved feed efficiency.

EFFECTIVE DATE: December 23, 1997.

FOR FURTHER INFORMATION CONTACT: Jeffrey M. Gilbert, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1602.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of ANADA's 200–209 and 200–215 that provide for combining approved salinomycin, bacitracin zinc, and roxarsone Type A medicated articles to make Type C medicated broiler feeds containing salinomycin 40 to 60 grams per ton (g/t), bacitracin zinc 10 to 50 g/t, and roxarsone 34.1 g/t. The Type C medicated feed is used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, increased rate of weight gain, and improved feed efficiency.

Alpharma Inc.'s ANADA 200–209 provides for using approved SACOX® (Hoechst-Roussel Vet's salinomycin ANADA 200–075), ALBAC® (Alpharma Inc.'s bacitracin zinc ANADA 200–223), and 3–NITRO® (Alpharma Inc.'s roxarsone NADA 7–891) Type A medicated articles to make the combination drug Type C medicated feeds. Alpharma Inc.'s ANADA 200–215 provides for using approved BIO-COX® (Hoffmann-LaRoche, Inc.'s salinomycin NADA 128–686), ALBAC® (Alpharma Inc.'s bacitracin zinc ANADA 200–223), and 3–NITRO® (Alpharma Inc.'s roxarsone NADA 7–891) Type A medicated articles to make the combination drug Type C medicated feeds.

Alpharma Inc.'s ANADA 200–209 is approved as a generic copy of Hoechst-Roussel Vet's ANADA 200–143. Alpharma Inc.'s ANADA 200–215 is approved as a generic copy of Hoffmann-LaRoche, Inc.'s NADA 139–190. The ANADA's are approved as of December 23, 1997, and the regulations are amended in 21 CFR 558.550(b)(1)(ix)(*c*) to reflect the approvals. The basis for approval is discussed in the freedom of information summaries.

This approval is for use of three single ingredient Type A medicated articles to make combination drug Type C medicated feeds. One ingredient, roxarsone, is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved form FDA 1900 is required to make Type C medicated feed from a Category II drug. Under section 512(m) of the act (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104–250), medicated feed applications have been replaced by a requirement for feed mill licenses. Therefore, use of salinomycin, bacitracin zinc, and roxarsone Type A medicated articles to make Type C medicated feeds as provided in ANADA's 200–209 and 200–215 is limited to manufacture in a licensed feed mill.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of each of these applications may be seen in the Dockets Management Branch (HFA–305), Food and Drug