Compliance: Required as indicated, unless accomplished previously.

To detect and correct fatigue cracking in the lower lugs of the barrel of the main landing gear (MLG), and consequent collapse of the MLG, accomplish the following:

(a) Perform an ultrasonic inspection to detect fatigue cracks of the lower lugs of the barrel of the MLG, in accordance with Messier-Dowty Service Bulletin 631–32–132, dated January 21, 1997, at the time specified in paragraph (a)(1) or (a)(2) of this AD, as applicable:

(1) Within 2 years after the last overhaul or repair of the lower lugs of the barrel of the MLG, or within 60 days after March 7, 1997 (the effective date of AD 97–04–09, amendment 39–9933), whichever occurs later; or

(2) Within 5 years after the installation of a new MLG barrel assembly, or within 60 days after the effective date of this AD, whichever occurs later.

(b) If, during any inspection required by this AD, no echo is detected, or if the echo is less than 20%, repeat the ultrasonic inspection thereafter at intervals not to exceed 900 landings.

(c) If, during any inspection required by this AD, the echo is greater than or equal to 20%, prior to further flight, replace the MLG barrel assembly with a new or serviceable MLG barrel assembly, in accordance with the service bulletin.

(1) If the damaged barrel assembly is replaced with an overhauled or repaired assembly, within 2 years after installation of that overhauled or repaired part, accomplish the actions specified in paragraph (a) of this AD.

(2) If the damaged barrel assembly is replaced with a new barrel assembly, within 5 years after installation of that new part, accomplish the actions specified in paragraph (a) of this AD.

(d) Modification of the lower lugs of the barrel of the MLG in accordance with Messier-Dowty Service Bulletin 631–32–133, dated February 24, 1997, as revised by Messier-Dowty Service Bulletin Change Notice No. 1, dated March 18, 1997, constitutes terminating action for the repetitive inspection requirements of this AD.

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

(f) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(g) The actions shall be done in accordance with Messier-Dowty Service Bulletin 631–32–133, dated February 24, 1997, as revised by Messier-Dowty Service Bulletin Change Notice No. 1, dated March 18, 1997; and Messier-Dowty Service Bulletin 631–32–132, dated January 21, 1997.

(1) The incorporation by reference of Messier-Dowty Service Bulletin 631–32–133, dated February 24, 1997, as revised by Messier-Dowty Service Bulletin Change Notice No. 1, dated March 18, 1997, is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The incorporation by reference of Messier-Dowty Service Bulletin 631–32–132, dated January 21, 1997, was approved previously by the Director of the Federal Register as of March 7, 1997 (62 FR 7665, February 20, 1997).

(3) Copies may be obtained from Aerospatiale, 316 Route de Bayonne, 31060 Toulouse, Cedex 03, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in French airworthiness directive 96–294(B)R1, dated September 10, 1997.

(h) This amendment becomes effective on January 7, 1998.

Issued in Renton, Washington, on December 15, 1997.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–33509 Filed 12–22–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 500

[Docket No. 95N–0417]

Carcinogenicity Testing of Compounds Used in Food-Producing Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations that set forth the requirements for the carcinogenicity testing of compounds used in food-producing animals. The amended regulations will eliminate the specific requirement that a sponsor must conduct oral, chronic, dose-response studies. This action is intended to allow FDA and sponsors greater flexibility in choosing the types of studies used for testing the carcinogenicity of compounds used in food-producing animals. The increased flexibility will make it easier and more economical for sponsors to complete required testing. These actions are part of FDA's continuing effort to achieve the objectives set forth in the President's ''National Performance Review'' 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.

EFFECTIVE DATE: February 23, 1998.

FOR FURTHER INFORMATION CONTACT: Margaret A. Miller, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0205.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 20, 1996 (61 FR 31468), FDA proposed to revise the requirements for the carcinogenicity testing of compounds used in food-producing animals as set forth in § 500.80(b) (21 CFR 500.80(b)) of the new animal drug approval regulations. The second sentence of § 500.80(b) of the existing regulation states, ''The bioassays that a sponsor conducts must be oral, chronic, dose-response studies and must be designed to assess carcinogenicity and to determine the quantitative aspects of any carcinogenic response.'' The proposed rule would revise the existing language to eliminate the words ''must be oral, chronic, dose-response studies and'' * * *.

When the existing regulation was issued, a chronic study was the standard test for carcinogenicity. However, advances in models used to assess carcinogenicity have been made in recent years. For example, scientists now agree that a chronic study, as required under current regulations, may not measure the appropriate time point necessary to assess carcinogenicity for some compounds. Study designs other than a chronic study may result in a better evaluation of the compound in a number of cases.

FDA recognized these scientific advances by proposing to remove the requirement for oral, chronic, dose-response studies so that sponsors would have the option of using other study designs when assessing the carcinogenicity of compounds used for food-producing animals. This proposed change would allow FDA and sponsors greater flexibility in choosing types of studies for testing the carcinogenicity of compounds used in food-producing animals, making it more economical and

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]

BILLING CODE 4160–01–F

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