action, and that no operator would accomplish this modification in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

SAAB Aircraft AB: Docket 96–NM–229–AD.

Applicability: Model SAAB 2000 series airplanes, equipped with an auxiliary power unit (APU) having part number 4500090, serial numbers SP–E941224, and SP–E941228 through SP–E951259 inclusive; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent auxiliary power unit (APU) failure, which could result in the inability of the APU to restart the engines in the event both engines quit operating during flight, accomplish the following:

(a) Within 60 days after the effective date of this AD: Replace the ignition exciter, part number 4950787, with an ignition exciter having part number 179420–2, in accordance with Saab Service Bulletin 2000–49–005, dated December 19, 1995.

(b) As of the effective date of this AD, no person shall install an ignition exciter having part number 4950787 on any airplane.

(c) 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, Standardization Branch, ANM–113, 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, Standardization Branch, ANM–113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(d) 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.

Issued in Renton, Washington, on May 2, 1997.

Neil D. Schalekamp,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–12040 Filed 5–7–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 511 and 514

[Docket No. 96N–0411]

New Animal Drugs for Investigational Use and New Animal Drug Applications; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to June 9, 1997 the comment period for the advance notice of proposed rulemaking (ANPRM) for investigational use new animal drug (INAD) regulations and the new animal drug applications (NADA) regulations that published in the **Federal Register** of November 21, 1996. The comment period is being reopened for the sole purpose of inviting interested persons to submit comments that will give FDA guidance in developing proposed regulations defining ''good study practices.'' Elsewhere in this issue of the **Federal Register**, FDA is publishing a related document, a proposed rule further defining adequate and well-controlled studies. The definition of adequate and well-controlled studies requires that such a study, when conducted in the target animal, be conducted in compliance with good study practices.

DATES: Written comments by June 9, 1997.

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: Herman M. Schoenemann, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1638.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 21, 1996 (61 FR 59209), FDA published an advance notice of proposed rulemaking announcing the agency's intention to propose revisions to the INAD regulations and the NADA regulations. The purpose of these revisions is to: (1) Implement the Animal Drug Availability Act of 1996 (ADAA) (Pub. L. 104–250) and (2) fulfill FDA's commitment as announced in the President's National

Performance Report, ''Reinventing the Regulation of Animal Drugs,'' May 1996. FDA solicited comments on all aspects of its proposed rulemaking relating to INAD and NADA regulations and requested comments on specific issues including defining ''adequate and well-controlled.''

Section 2(e) of the ADAA, enacted on October 9, 1996, directed FDA to issue, within 6 months of its enactment, proposed regulations to further define the term ''adequate and well-controlled'' to require that field investigations be designed and conducted in a scientifically sound manner, taking into account practical conditions in the field and differences between field conditions and laboratory conditions. Elsewhere in this issue of the **Federal Register**, FDA has issued a proposed rule further defining adequate and well-controlled studies. As proposed, one characteristic of an adequate and well-controlled study is that such a study, when conducted in the target animal, be conducted in compliance with good study practices. As explained in the preamble to the proposed regulation defining adequate and well-controlled studies, FDA intends to define good study practices when the agency publishes the revised INAD regulations.

FDA is reopening the comment period on the ANPRM for the sole purpose of inviting interested persons to submit comments which will give FDA guidance in developing proposed regulations defining good study practices. The agency is particularly interested in specific comments explaining which study practices, including practices such as those specified in good laboratory practices or specific practices recommended by the Center for Veterinary Medicine during the conduct studies or in guidance, could not be followed, in whole or in part, when studies are conducted under actual use conditions in field studies. These comments should include specific examples whenever possible.

Interested persons may, on or before June 9, 1997 submit to the Dockets Management Branch (address above) written comments regarding good study practices. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 29, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–11845 Filed 5–7–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. 97N–0141]

Adequate and Well-Controlled Studies for Investigational Use and Approval of New Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA), as directed by the Animal Drug Availability Act of 1996 (ADAA), is publishing a proposed regulation to further define the term ''adequate and well-controlled'' to require that field investigations be designed and conducted in a scientifically sound manner. Elsewhere in this issue of the **Federal Register**, FDA is reopening docket number 96N–0411 to receive comments regarding a concept, ''good study practices,'' that is related to the definition of adequate and well-controlled studies.

DATES: Written comments by July 22, 1997.

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: Herman M. Schoenemann, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1638.

SUPPLEMENTARY INFORMATION:

I. Background

Congress enacted the ADAA (Pub. L. 104–250) on October 9, 1996. Section 2(e) of the ADAA directs FDA to issue, within 6 months of its enactment, proposed regulations to further define the term ''adequate and well-controlled'' to require that field investigations be designed and conducted in a scientifically sound manner, taking into account practical conditions in the field and differences between field conditions and laboratory conditions. Although FDA believes that the definition of adequate and well-controlled is meaningful only when considered within the context of the entire set of regulations that govern the investigational use and approval of new animal drugs, FDA is publishing this proposed definition of adequate and well-controlled studies separately because of the statutory timeframe set forth in the ADAA. FDA intends to issue proposed revised investigational use new animal drug (INAD) regulations followed by proposed revised regulations governing new animal drug applications. These proposals, intended to further implement the ADAA and the Center for Veterinary Medicine's (CVM) commitment to reinvent the animal drug approval process and facilitate the approval of new animal drugs, will give context to the definition of adequate and well-controlled studies.

II. Adequate and Well-Controlled Studies

FDA has long considered that the characteristics embodied in 21 CFR 314.126 and § 514.111(a)(5)(ii) (21 CFR 514.111(a)(5)(ii)) are the essentials of an adequate and well-controlled study. Discussions held between FDA and members of the Coalition for Animal Health (Coalition) prior to enactment of the ADAA and comments from the Animal Health Institute in response to the advance notice of proposed rulemaking published November 21, 1996 (61 FR 59209), made it clear that some members of the regulated industry are concerned that certain scientific principles and practices may be difficult to apply in testing new animal drugs under field conditions. In response, FDA evaluated the extent to which the characteristics in § 514.111(a)(5)(ii) represent sound scientific principles essential for adequate and well-controlled studies. After careful consideration of the characteristics in light of the concerns expressed, FDA believes that the characteristics set forth in § 514.111(a)(5)(ii), with minor modifications, remain sound scientific principles essential for all adequate and well-controlled studies whether conducted under laboratory or field conditions. (See definition of substantial evidence, section 512(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(d)(3))). The agency is proposing to replace current § 514.111(a)(5)(ii) with new proposed § 514.117, which contains minor revisions to the current regulation on adequate and well-controlled studies.

The primary purpose of conducting adequate and well-controlled studies is, and has always been, to distinguish the effect of the drug from other influences, such as spontaneous change in the