DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 91

[Docket No. FAA–2001–11133; Amendment No. 91–282]

RIN 2120–AH19

Certification of Aircraft and Airmen for the Operation of Light-Sport Aircraft; Correction

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: The FAA is correcting an inadvertent error in a final regulation published in the **Federal Register** of Tuesday, July 27, 2004 (69 FR 44772). The regulation related to the certification of aircraft and airmen for the operation of light-sport aircraft. The correction is to the section concerning aircraft having experimental certificates: Operating limitations.

DATES: The regulation is effective September 4, 2004.

FOR FURTHER INFORMATION CONTACT: Susan Gardner, Flight Standards Service, General Aviation and Commercial Division (AFS–800), Federal Aviation Administration, 800 Independence Ave., SW., Washington, DC 20591; telephone 907–271–2034, or 202–267–8212.

SUPPLEMENTARY INFORMATION: In FR Doc. 04–16577 appearing on page 44772 in the **Federal Register** of Tuesday, July 27, 2004, make the following correction:

§ 91.319 [Corrected]

■ On page 44881, in the first column, amendment number 64, ''Amend § 91.319 by redesignating paragraph (e) as paragraph (h) and adding new paragraphs (e), (f), and (g) to read as follows:'' is corrected to read ''Amend § 91.319 by redesignating paragraph (e) as paragraph (i) and adding new paragraphs (e), (f), (g), and (h) to read as follows:''.

Issued in Washington, DC, on August 12, 2004.

Anthony F. Fazio,

Director, Office of Rulemaking.

[FR Doc. 04–18904 Filed 8–17–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. 2000N–1399]

Presubmission Conferences

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this final rule to amend its new animal drug regulations to implement a new provision of the Federal Food, Drug, and Cosmetic Act (the act). Under this new provision of the act, as amended by the Animal Drug Availability Act of 1996 (ADAA), any person intending to file a new animal drug application (NADA) or supplemental NADA or to investigate a new animal drug is entitled to one or more conferences with FDA to reach an agreement establishing a submission or investigational requirement. This final rule describes the procedures for requesting, conducting, and documenting such presubmission conferences.

DATES: This rule is effective November 1, 2004.

FOR FURTHER INFORMATION CONTACT: Gail Schmerfeld, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1796, e-mail: *gschmer1@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Congress enacted the ADAA on October 9, 1996. Section 512(b)(3) of the act (21 U.S.C. 360b(b)(3)), as amended by the ADAA, provides that any person intending to file an NADA or supplemental NADA or to request an investigational exemption is entitled to one or more conferences with FDA prior to such submission to reach an agreement establishing a submission or investigational requirement. In the **Federal Register** of August 25, 2000 (65 FR 51782), we proposed amending the new animal drug applications regulations in part 514 (21 CFR part 514) to describe the procedures to be followed for requesting, conducting, and documenting presubmission conferences. Under the proposed rule and final rule, persons intending to file an abbreviated new animal drug application (ANADA) as well as persons intending to file an NADA or supplemental NADA are entitled to request presubmission conferences. FDA provided 75 days for public comment on the proposed rule.

II. Comments on the Proposed Rule

We received four letters from government, industry, and trade associations commenting on the proposed presubmission conference rule. Our response to the comments, grouped by codified section, follows.

A. General Comments

(Comment 1) Two comments assert that presubmission conferences under section 512(b)(3) of the act represent a fundamental change in the manner the agency is to operate and a new way for the agency to do business.

(Response) FDA disagrees with these comments. Presubmission conferences under 512(b)(3) of the act do not represent a fundamental change in the manner we operate. Although there was no statutory or regulatory entitlement to a presubmission conference prior to enactment of the ADAA, FDA's Center for Veterinary Medicine (CVM) had already been encouraging sponsors of NADAs to participate in conferences with us to discuss in detail what studies would be necessary to demonstrate the safety and effectiveness of particular new animal drugs being investigated. We found, as a result of this direct communication during the development and review of new animal drugs, that fewer unusable studies were conducted and there were fewer delays in the review process. Although such agreements were not legally binding, we attempted to be sensitive to industry's concern that we not change such requirements without justification. Our goal was to not change requirements unless we became aware of new information that suggested such requirements may no longer support approval.

B. Definitions (§ 514.3)

In the proposed rule, the preamble discusses definitions in proposed § 514.3. However, the *Definitions* section in the codified text in the proposed rule was mistakenly numbered § 514.2. The definitions added by this final rule will be added to existing § 514.3 *Definitions* in alphabetical order.

In the proposed rule, *potential applicant* was defined to mean any person intending to: (1) Investigate a new animal drug under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act), (2) file a new animal drug application (NADA) or supplemental NADA under 512(b)(1) of the act, or (3) file an abbreviated new animal drug