(3) Reporting Requirements: For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information


Material Incorporated by Reference

(i) You must use STEMME F & D Service Bulletin A31–10–082, AM-Index: 01.a, dated November 30, 2007, and STEMME F & D Service Bulletin A31–10–083, AM-Index: 01.a, dated February 26, 2008, to do the actions required by this AD, unless the AD specifies otherwise.

(ii) The Director of the Federal Register approved the incorporation by reference of STEMME F & D Service Bulletin A31–10–083, AM-Index: 01.a, dated February 26, 2008, under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) On February 20, 2008 (73 FR 5733, January 31, 2008), the Director of the Federal Register previously approved the incorporation by reference of STEMME F & D Service Bulletin A31–10–083, AM-Index: 01.a, dated February 26, 2008, under 5 U.S.C. 552(a) and 1 CFR part 51.

(3) For service information identified in this AD, contact STEMME GmbH & Co. KG, Flugplatzstr[beta]e F. Z, Nr. 7, 15344 Strausberg, Federal Republic of Germany.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Greg Davison, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4130; fax: (816) 329–409. Before using any approved AMOC on any sailplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) Airworthiness Product: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Butorphanol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

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 Lloyd, Inc. The ANADA provides for the veterinary prescription use of butorphanol tartrate injectable solution in horses for the relief of pain.

DATES: This rule is effective June 2, 2008.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Lloyd, Inc., 604 West Thomas Ave., Shenandoah, IA 51601, filed ANADA 200–332 that provides for the veterinary prescription use of BUTORPHIC (butorphanol tartrate) Injection in horses for the relief of pain associated with colic and postpartum pain. Lloyd, Inc.’s BUTORPHIC Injection is approved as a generic copy of TORBUGESIC, sponsored by Fort Dodge Animal Health, Division of Wyeth, under NADA 135–780. The ANADA is approved as of May 1, 2008, and 21 CFR 522.246 is amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

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.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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 redecoded 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:


§ 522.246 [Amended]

2. In paragraph (b)(3) of § 522.246, remove “057926 and 059130” and in its place add “057926, 059130, and 061690”.

Dated: May 21, 2008.

Bernadette Dunham,
Director, Center for Veterinary Medicine.

[FR Doc. E8–12160 Filed 5–30–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. FDA–2008–N–0148]

Medical Devices; Hearing Aids; Technical Data Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing hearing aid labeling to reference the most recent version of the consensus standard used to determine the technical data to be included in labeling for hearing aids. We are amending the regulations to require that manufacturers may use state-of-the-art methods to provide technical data in hearing aid labeling. FDA is also amending the regulations to update an address and remove an outdated requirement. FDA is amending the regulations in accordance with its direct final rule procedures. Elsewhere in this issue of the Federal Register, we are publishing a companion proposed rule under FDA’s usual procedures for notice and comment rulemaking to provide a procedural framework to finalize the rule in the event we receive a significant adverse comment and withdraw this direct final rule. DATES: This rule is effective October 15, 2008. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in § 801.420(c)(4) (21 CFR 801.420(c)(4)) as of October 15, 2008. Submit written or electronic comments by August 18, 2008. If we receive no significant adverse comments within the specified comment period, we intend to publish a document confirming the effective date of the final rule in the Federal Register within 30 days after the comment period ends.

FDA is amending the regulations to require that manufacturers may use technical data in hearing aid labeling.

We are amending the regulations to provide a method of ascertaining hearing aid characteristics. The standard established measurement methods and other labeling be determined according to the test procedures established by the Acoustical Society of America (ASA) in the American National Standard “Specification of Hearing Aid Characteristics.” ANSI S3.22–1976 (ASA 70–1976), which was incorporated by reference in the regulation. ANSI S3.22 (ASA 70–1976) established measurement methods and specifications for several important hearing aid characteristics. The standard provided a method of ascertaining whether a hearing aid, after being manufactured and shipped, met the specifications and design parameters stated by the manufacturer for a particular model, within the tolerance stated by the standard.


SUPPLEMENTARY INFORMATION:

I. What Is the Background of the Rulemaking?

In the Federal Register of February 15, 1977 (the 1977 final rule) (42 FR 9286), FDA published a final rule establishing requirements for professional and patient labeling of hearing aids and governing conditions for sale of hearing aids (§ 801.420 and § 801.421 (21 CFR 801.421)). The regulations became effective on August 15, 1977. Section 801.421(b)(1) of the current regulations provides that, before the sale of a hearing aid to a prospective user, a hearing aid dispenser is to provide the prospective user with a copy of the User Instructional Brochure. Current § 801.420(c)(4) requires that technical data useful in selecting, fitting, and checking the performance of a hearing aid be provided in the brochure or in separate labeling that accompanies the device. The 1977 final rule further required that the technical data values provided in the brochure or other labeling be determined according to the test procedures established by the Acoustical Society of America (ASA) in the American National Standard “Specification of Hearing Aid Characteristics.” ANSI S3.22–1976 (ASA 70–1976), which was incorporated by reference in the regulation.

ANSI S3.22 (ASA 70–1976) established measurement methods and specifications for several important hearing aid characteristics. The standard provided a method of ascertaining whether a hearing aid, after being manufactured and shipped, met the specifications and design parameters stated by the manufacturer for a particular model, within the tolerance stated by the standard.

II. Final Rule

After consideration of the comments received, we are finalizing the rule. Notice and comment rulemaking to provide a procedural framework to finalize the rule in the event we receive a significant adverse comment and withdraw this direct final rule took place from March 28, 2008, through June 10, 2008. We received comments from the Acoustical Society of America, the American National Standards Institute (ANSI) Human Factors/Engineering Committee, the Hearing Aid Industry, the Heartronics Corporation, the Hearing Aid Association of America, the Hearing Industries Association, and the National Association of the Deaf. None of the comments we received raised significant issues. Therefore, we are finalizing the rule without change.