

(3) *For all sailplanes affected by this AD:* If any leak is found during the inspection required in paragraph (f)(2) of this AD, before further flight, repair the leak following an FAA-approved repair procedure and replace all STEMME part number (P/N) M476 single-ear clamps in the fuel system with P/N 10M-181 single-ear clamps. Do the replacements following STEMME F & D Service Bulletin A31-10-083, Am-Index: 01.a, dated February 26, 2008.

(4) After June 23, 2008 (the effective date of this AD), do not install plastic "T" and "Y" shape connectors and P/N M476 single-ear clamps in the fuel system.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows:

(1) The MCAI and the service information require replacing all P/N M476 single-ear clamps in the fuel system with P/N 10M-181 single-ear clamps within the next 12 months after the effective date.

(2) This AD is considered an interim action because we are not including a mandatory requirement to replace all STEMME P/N M476 single-ear clamps in the fuel system with P/N 10M-181 single-ear clamps on all affected sailplanes unless a leak in the fuel system is found. The Administrative Procedure Act does not permit the FAA to "bootstrap" a long-term requirement into an urgent safety of flight action where the rule becomes effective at the same time the public has the opportunity to comment. The short-term action and the long-term action are analyzed separately for justification to bypass prior public notice.

(3) After issuing this AD, we may initiate further AD action (notice of proposed rulemaking followed by a final rule) to require replacing all P/N M476 single-ear clamps in the fuel system with P/N 10M-181 single-ear clamps on all affected sailplanes by a specified time. Credit will be given in any subsequent action for the replacement done under this AD.

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) *Airworthy 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.

(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

(h) Refer to MCAI European Aviation Safety Agency (EASA) Emergency AD No. 2008-0053-E, dated March 5, 2008; 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, for 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.

(1) 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 A31-10-082, AM-Index: 01.a, dated November 30, 2007.

(3) For service information identified in this AD, contact STEMME GmbH & Co. KG, Flugplatzstra[3]e F 2, Nr. 7, 15344 Strausberg, Federal Republic of Germany.

(4) You may review copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Kansas City, Missouri on May 23, 2008.

David R. Showers,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8-12115 Filed 5-30-08; 8:45 am]

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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 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.

§ 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 on this direct final rule ends. If we receive any timely significant adverse comment, we will withdraw this final rule in part or in whole by publication of a document in the **Federal Register** within 30 days after the comment period ends.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2008–N–0148, by any of the following methods: *Electronic Submissions*

Submit electronic comments in the following way:

• **Web:** Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

• **FAX:** 301–827–6870.

• **Mail/Hand delivery/Courier**

[For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No. for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number(s), found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Eric A. Mann, Center for Devices and

Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4242.

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.

In 1982, ASA revised the standard (ANSI S3.22–1982) (ASA 70–1982). In a final rule published in the **Federal Register** of July 24, 1985 (50 FR 30153), FDA incorporated the revised standard into § 801.420(c)(4). ASA revised the standard again in 1987 (ANSI S3.22–1987) (ASA 70–1987). In a final rule published in the **Federal Register** of December 21, 1989 (54 FR 52395), FDA incorporated the revised standard into § 801.420(c)(4). In 1996, ASA revised the standard again (ANSI S3.22–1996) (ASA 70–1996). In a final rule published in the **Federal Register** of November 3, 1999 (64 FR 59618), FDA incorporated the revised standard into § 801.420(c)(4).