

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-P-0528]

Determination That CITANEST (Prilocaine Hydrochloride) Injection, 1%, 2%, and 3%, and CITANEST PLAIN (Prilocaine Hydrochloride) Injection, 4%, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that CITANEST (prilocaine hydrochloride (HCl)) Injection, 1%, 2%, and 3%, and CITANEST PLAIN (prilocaine HCl) Injection, 4%, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for prilocaine HCl injection, 1%, 2%, and 3%, and prilocaine HCl injection, 4%, if all legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: S. Mitchell Weitzman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6318, Silver Spring, MD 20993-0002, 301-796-3511.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products with Therapeutic Equivalence Evaluations,"

which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

CITANEST (prilocaine HCl) Injection, 1%, 2%, and 3%, and CITANEST PLAIN (prilocaine HCl) Injection, 4%, are the subject of NDA 14-763, held by AstraZeneca, and initially approved on November 18, 1965. CITANEST and CITANEST PLAIN are indicated for the production of local anesthesia in infiltration procedures, peripheral nerve blocks, and epidural or caudal blocks.

In a letter dated August 28, 2002, AstraZeneca notified FDA that they had decided to withdraw NDA 14-763 for CITANEST (prilocaine HCl) Injection, 1%, 2%, and 3%; CITANEST PLAIN (prilocaine HCl) Injection, 4%; and CITANEST FORTE (epinephrine bitartrate and prilocaine HCl) Injection, 0.005 milligrams/milliliter and 4%,¹ in accordance with 21 CFR 314.150(c). FDA moved the drug products to the "Discontinued Drug Product List" section of the Orange Book. In the **Federal Register** of August 18, 2003 (68 FR 49481), FDA announced that it was withdrawing approval of NDA 14-763, effective September 17, 2003.

Lachman Consultant Services, Inc., submitted a citizen petition dated September 25, 2008 (Docket No. FDA-2008-P-0528), under 21 CFR 10.30, requesting that the Agency determine whether prilocaine HCl injections, 1%, 2%, 3%, and 4%, NDA 14-763, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CITANEST (prilocaine HCl) Injection, 1%, 2%, and 3%, and CITANEST PLAIN (prilocaine HCl)

¹This notice does not include a determination as to whether CITANEST FORTE, approved under NDA 14-763, was withdrawn for reasons of safety or efficacy.

Injection, 4%, were not withdrawn for reasons of safety or effectiveness.

The petitioner has identified no data or other information suggesting that CITANEST (prilocaine HCl) Injection, 1%, 2%, and 3%, and CITANEST PLAIN (prilocaine HCl) Injection, 4%, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CITANEST (prilocaine HCl) Injection, 1%, 2%, and 3%, and CITANEST PLAIN (prilocaine HCl) Injection, 4%, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that CITANEST (prilocaine HCl) Injections, 1%, 2%, and 3%, and CITANEST PLAIN (prilocaine HCl) Injection, 4%, were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CITANEST (prilocaine HCl) Injection, 1%, 2%, and 3%, and CITANEST PLAIN (prilocaine HCl) Injection, 4%, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to CITANEST (prilocaine HCl) Injection, 1%, 2%, and 3%, and CITANEST PLAIN (prilocaine HCl) Injection, 4%, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 13, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-6501 Filed 3-16-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0226]

Guidance for Industry, Third Parties and Food and Drug Administration Staff; Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program.” This guidance document is intended to provide information on the implementation of the Food and Drug Administration Amendments Act of 2007 (FDAAA), which amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This guidance document describes how FDA’s Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) are implementing this provision of the law. The Pilot Program will be effective June 5, 2012.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled “Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002 or Office of Communication, Outreach and Development (HFM–40), 1401 Rockville Pike, suite 200N, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kimberly A. Trautman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5400, Silver Spring, MD 20993–0002, 301–796–5515; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301–827–6210.

I. Background

This guidance document is intended to provide information on the implementation of section 228 of FDAAA (Pub. L. 110–85), which amends section 704(g)(7) of the FD&C Act (21 U.S.C. 374(g)(7)). Under this guidance document, a device manufacturer whose establishment has been audited under one of the regulatory systems implemented by the Global Harmonization Task Force (GHTF) founding members¹ using International Organization for Standardization (ISO) 13485:2003 “Medical devices—Quality management systems—Requirements for regulatory purposes” and ISO 13485:2003 Technical Corrigendum 1:2009 “Medical devices—Quality management systems—Requirements for regulatory purposes,” (ISO 13485:2003) or a national adoption of this standard, e.g., EUROPEAN STANDARD EN ISO 13485 July 2003 + AC August 2009, “Medical devices—Quality management systems—Requirements for regulatory purposes” (ISO 13485:2003 + Cor 1:2009) (EN ISO 13485:2003/AC:2009), National Standard of Canada CAN/CSA–ISO 13485:03 (ISO 13485:2003) “Medical devices — Quality management systems—Requirements for regulatory purposes” (Reaffirmed 2008) (CAN/CAS ISO 13485 13485:2003)), may voluntarily submit the resulting audit report to FDA. If, based on that report, FDA determines that there is minimal probability—in light of the relationship between the quality system deficiencies observed and the particular device and manufacturing processes involved—that the establishment will produce nonconforming and/or defective finished devices,² then FDA intends to use the audit results as part of its risk assessment to determine whether that establishment can be removed from FDA’s routine work plan for 1 year. The voluntarily submitted ISO 13485:2003 “Medical devices—Quality management systems—Requirements for regulatory purposes” and ISO 13485:2003 Technical Corrigendum 1:2009 “Medical devices—Quality management systems—Requirements for regulatory purposes,”

¹ The GHTF founding members auditing systems include: The Canadian Medical Devices Conformity Assessment System; the European Union Notified Body Accreditation System; the Therapeutics Goods Administration of Australia Inspectorate; and the Japanese Ministry of Health, Labour and Welfare System for Medical Devices and In-Vitro Diagnostics.

² See February 2, 2011, Compliance Program (CP) 7382.845 Inspection of Medical Device Manufacturers Part V <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072753.htm>.

(ISO 13485:2003) audit report provides FDA a degree of assurance of compliance with basic and fundamental quality management system requirements for medical devices.

The medical device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program outlined in the guidance is another way in which FDA may leverage audits performed by other GHTF regulators and their accredited third parties in order to assist FDA in setting risk-based inspectional priorities.

The draft guidance document entitled, “Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program” was published for comment in the **Federal Register** of May 20, 2010 (75 FR 28257). Comments on the collection information were due July 19, 2010, and comments on the draft guidance document were due by August 18, 2010.

FDA received comments and suggestions to pilot this program for a period of time; an evaluation will follow to allow both FDA and industry to work out potential issues, obstacles, and resource allocations. FDA agrees and has decided to pilot this ISO 13485 Voluntary Audit Report Submission Program for a period of 2 years effective June 5, 2012. FDA will then evaluate the program and report on the findings and any issues or suggested changes.

II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on “Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program.” It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or from the CBER Internet site at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. To receive “Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program” you may either send an email request to dsmica@fda.hhs.gov to

receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1746 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). The collection(s) of information in this guidance was approved under OMB control number 0910-0700. This final guidance also refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 820 are currently approved under OMB control number 0910-0073 and the collections of information for the Inspection by Accredited Persons Program are currently approved under OMB control number 0910-0569.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 13, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-6503 Filed 3-16-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 10, 2012, from 8 a.m. to 5 p.m.

Location: DoubleTree by Hilton Hotel Washington, DC-Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel telephone number is 301-589-5200.

Contact Person: Paul Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: EMDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the safety and efficacy of new drug application (NDA) 22-529 (lorcaserin hydrochloride) tablets, manufactured by Arena Pharmaceuticals, Inc., as an adjunct to diet and exercise for weight management in patients with a body mass index (BMI) equal to or greater than 30 kilograms (kg) per square meter or a BMI equal to or greater than 27 kg per square meter if accompanied by weight-related comorbidities.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending

before the committee. Written submissions may be made to the contact person on or before April 26, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 18, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 19, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Paul Tran at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 13, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.