Federal Register: Draft Guidance for Industry and Food and Drug Administration Staff; Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays; Availa...

U.S. Food & Drug Administration

[Federal Register: August 6, 2010 (Volume 75, Number 151)] [Notices] [Page 47603-47604] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr06au10-84]
---------- DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration [Docket No. FDA-2010-D-0395] Draft Guidance for Industry and Food and Drug Administration Staff; Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays; Availability AGENCY: Food and Drug Administration, HHS. ACTION: Notice. ---------- SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ``Draft Guidance for Industry and FDA Staff; Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays.'' This draft guidance document discusses information to be included in premarket notifications for lamotrigine or zonisamide assays. This draft guidance is not final nor is it in effect at this time. DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 4, 2010. ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ``Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays'' to the Division of Small Manufacturers, International,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. 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 Submit electronic comments on the draft guidance to http://www.regulations.gov [1]. 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: Avis Danishefsky, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5620, Silver Spring, MD 20993-0002, 301- 796-6142. SUPPLEMENTARY INFORMATION: I. Background FDA is issuing this draft guidance document to describe its current thinking concerning issues that should be addressed in premarket notifications for assays intended to quantitate the anti-seizure drugs lamotrigine and zonisamide in serum. The Therapeutic Drug Monitoring (TDM) Roundtable of the American Association of

Clinical Chemists (AACC) submitted to FDA recommendations for lamotrigine assays. Many of the recommendations in this draft guidance document are consistent with the AACC TDM Roundtable recommendations. Some of the general concepts in this guidance may also be helpful in preparing 510(k) submissions for other therapeutic drug assays previously cleared by FDA and classified within 21 CFR part 862, subpart D. II. Significance of Guidance This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on therapeutic drug assays that measure lamotrigine or zonisamide. 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 draft guidance may do so by using the Internet. To receive ``Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays,'' you may either send an e-mail request to dsmica@fda.hhs.gov [2] 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 1654 to identify the guidance you are requesting. A search capability for all CDRH guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm [3]. Guidance documents are also available at http://www.regulations.gov [1]. IV. Paperwork Reduction Act of 1995 This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR 809.10 have been approved under OMB control number 0910-0485. 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. It is no longer necessary to send two copies of mailed 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: August 2, 2010. Nancy Stade, Acting Associate Director for Regulations and Policy, Center for Devices and Radiological Health. [FR Doc. 2010-19419 Filed 8-5-10; 8:45 am] BILLING CODE 4160-01-S

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