comment period.[4] In addition, NAESB considers requests for waivers of the charges on a case-by-case basis depending on need.

Dated: January 15, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–01237 Filed 1–21–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2014–N–1021]

RIN 0910–AH00

Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: In the **Federal Register** of November 18, 2015 (80 FR 71990), the Food and Drug Administration (FDA) published a proposed rule entitled, ''Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods.'' Due to an inadvertent error, the publication contained conflicting dates for submission of comments under the Paperwork Reduction Act of 1995. This notice corrects that error.

DATES: Submit either electronic or written comments on information collection issues under the PRA by February 22, 2016.

ADDRESSES: Submit comments on information collection issues to the Office of Management and Budget in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or email to *oira_submission@omb.eop.gov.* All comments should be identified with the title ''Recordkeeping Requirements for Gluten-Free Labeling of Fermented or Hydrolyzed Foods.''

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On November 18, 2015 (80 FR 71990), the Food and Drug Administration (FDA) published a proposed rule entitled, ''Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods.'' In the **DATES** section of the proposed rule, we provided a 30-day period for submitting comments with respect to the information collection issues under the Paperwork Reduction Act of 1995 (PRA). However, in the PRA discussion for the proposed rule, an error was made that provided 60 days for PRA comments. To address this error, we have reopened the comment period for the information collection provisions of the proposed rule. Accordingly, comments regarding information collection issues may be received until February 22, 2016. The comment period for all other aspects of the proposed rule remains unchanged where comments may be submitted until February 16, 2016.

Dated: January 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01177 Filed 1–21–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2014–N–1209]

Neurological Devices; Reclassification of Cranial Electrotherapy Stimulator Intended To Treat Insomnia and/or Anxiety; Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator Intended To Treat Depression

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed administrative order to reclassify the cranial electrotherapy stimulator (CES) devices intended to treat insomnia and/or anxiety, a preamendments class III device, into class II (special controls) and subject to premarket notification, and to require the filing of a premarket approval application (PMA) for CES devices intended to treat depression. FDA is proposing the reclassification of CES devices intended to treat insomnia and/or anxiety under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) based on new information pertaining to the device. This proposed action would implement certain statutory requirements. FDA is also clarifying the identification for CES devices in this proposed order by identifying CES as a prescription device that applies electrical current that is not intended to induce a seizure to a patient's head to treat psychiatric conditions. This clarification distinguishes CES from electroconvulsive therapy (ECT).

DATES: Submit either electronic or written comments on this proposed order by April 21, 2016. See sections IX and XVII of this document for, respectively, the proposed dates when the new requirements apply and the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

[4] Procedures for non-members to evaluate work products before purchasing, *https://www.naesb.org/misc/NAESB_Nonmember_Evaluation.pdf.*