

occasionally may be unclear, or the information may not be strictly relevant or necessary to a specific investigation. In the interests of effective law enforcement, it is appropriate to retain all information that may aid in establishing patterns of unlawful activity.

(d) From subsection (e)(2) (Collection of Information from Individuals) because requiring that information be collected from the subject of an investigation would alert the subject to the nature or existence of the investigation, thereby interfering with that investigation and related law enforcement activities.

(e) From subsection (e)(3) (Notice to Subjects) because providing such detailed information could impede law enforcement by compromising the existence of a confidential investigation or reveal the identity of witnesses or confidential informants.

(f) From subsections (e)(4)(G), (e)(4)(H), and (e)(4)(I) (Agency Requirements) and (f) (Agency Rules), because portions of this system are exempt from the individual access provisions of subsection (d) for the reasons noted above, and therefore DHS is not required to establish requirements, rules, or procedures with respect to such access. Providing notice to individuals with respect to existence of records pertaining to them in the system of records or otherwise setting up procedures pursuant to which individuals may access and view records pertaining to themselves in the system would undermine investigative efforts and reveal the identities of witnesses, and potential witnesses, and confidential informants.

(g) From subsection (e)(5) (Collection of Information) because with the collection of information for law enforcement purposes, it is impossible to determine in advance what information is accurate, relevant, timely, and complete. Compliance with subsection (e)(5) would preclude DHS agents from using their investigative training and exercise of good judgment to both conduct and report on investigations.

(h) From subsection (e)(8) (Notice on Individuals) because compliance would interfere with DHS's ability to obtain, serve, and issue subpoenas, warrants, and other law enforcement mechanisms that may be filed under seal and could result in disclosure of investigative techniques, procedures, and evidence.

(i) From subsection (g) (Civil Remedies) to the extent that the system is exempt from other specific subsections of the Privacy Act.

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Dated: January 12, 2016.

Karen L. Neuman

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2016-01169 Filed 1-21-16; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 284

[Docket No. RM96-1-040]

Standards for Business Practices of Interstate Natural Gas Pipelines

AGENCY: Federal Energy Regulatory Commission. DOE.

ACTION: Proposed rule; request for comment on filing.

SUMMARY: Take notice that on January 11, 2016, the North American Energy Standards Board (NAESB) filed a report with the Commission stating it had approved a minor correction to Standard No. 1.3.22 (ii) of Version 3.0 of the NAESB Wholesale Gas Quadrant standards, which were incorporated by reference in the Commission's regulations by order issued by the Commission on October 16, 2015. Comments are invited on whether to incorporate this minor correction by reference in the Commission's regulations.

DATES: Comments are due on or before February 10, 2016.

ADDRESSES: Comments, identified by docket number, may be filed in the following ways:

- *Electronic Filing through <http://www.ferc.gov>.* Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format.

- *Mail/Hand Delivery:* Those unable to file electronically may mail or hand-deliver comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

FOR FURTHER INFORMATION CONTACT: Gary D. Cohen (legal issues), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, Telephone: (202) 502-8321, Email: gary.cohen@ferc.gov.

SUPPLEMENTARY INFORMATION: Comments are requested on whether to incorporate by reference the following NAESB Wholesale Gas Quadrant Standard into § 284.12 of the Commission's regulations: Nominations Related Standards (Version 3.0, November 14, 2014, with minor corrections applied through June 29, 2015 and MC15021 effective November 25, 2015).

Office of Management and Budget Circular A-119 (section 11) (February 10, 1998) provides that federal agencies

should publish a request for comment in a Notice of Proposed Rulemaking when the agency is seeking to issue or revise a regulation proposing to adopt a voluntary consensus standard or a government-unique standard. Standard 1.3.22 would be incorporated by reference.

The Office of the Federal Register requires agencies incorporating material by reference in final rules to discuss, in the preamble of the final rule, the ways that the materials it incorporates by reference are reasonably available to interested parties and how interested parties can obtain the materials.¹ The regulations also require agencies to summarize, in the preamble of the final rule, the material it incorporates by reference. Standard 1.3.22 (ii) establishes the scheduled quantity when no response is received for a request for confirmation. Our regulations provide that copies of the NAESB standards incorporated by reference may be obtained from the North American Energy Standards Board, 801 Travis Street, Suite 1675, Houston, TX 77002, Phone: (713) 356-0060. NAESB's Web site is at <http://www.naesb.org/>. Copies may be inspected at the Federal Energy Regulatory Commission, Public Reference and Files Maintenance Branch, 888 First Street NE., Washington, DC 20426, Phone: (202) 502-8371, <http://www.ferc.gov>.

The procedures used by NAESB make its standards reasonably available to those affected by the Commission regulations, which is comprised of entities that have the means to acquire the information they need to effectively participate in Commission proceedings. Participants can join NAESB, for an annual membership cost of only \$7,000, which entitles them to full participation in NAESB and enables them to obtain these standards at no additional cost.² Non-members who have purchased the standards may obtain the Minor Correction for free, non-members who have not purchased the standards may obtain the Standards Manual for standard 1.3.22 by email for \$250 per Manual.³ Nonmembers also may obtain the complete set of Standards Manuals, Booklets, and Contracts on CD for \$2,000. NAESB also provides a free electronic read-only version of the standards for a three business day period or, in the case of a regulatory comment period, through the end of the

¹ 1 CFR 51.5. See Incorporation by Reference, 79 FR 66267 (Nov. 7, 2014).

² North American Energy Standards Board Membership Application, <https://www.naesb.org/pdf4/naesbapp.pdf>.

³ NAESB Materials Order Form, <https://www.naesb.org/pdf/ordform.pdf>.

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 oir_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]

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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."

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