own business proprietary information, on persons on the APO service list, or the public version of such a document on persons on the public service list, may be made by facsimile transmission or other electronic transmission process, with the consent of the person to be served.

* * * * *

(g) *Certifications.* A person must file with each submission containing factual information the certification in paragraph (g)(1) of this section and, in addition, if the person has legal counsel or another representative, the certification in paragraph (g)(2) of this section:

(1) For the person officially responsible for presentation of the factual information:

I, (name and title), currently employed by (person), certify that (1) I have read the attached submission, and (2) the information contained in this submission is, to the best of my knowledge, complete and accurate.

* * * * *

6. Section 351.304 is amended by revising paragraphs (b), (c), (d)(1) introductory text and (d)(1)(iv) to read as follows:

§ 351.304 Establishing business proprietary treatment of information.

* * * * *

(b) *Identification of business proprietary information*—(1) *In general.* A person submitting information must identify the information for which it claims business proprietary treatment by enclosing the information within single brackets. The submitting person must provide with the information an explanation of why each item of bracketed information is entitled to business proprietary treatment. A person submitting a request for business proprietary treatment also must include an agreement to permit disclosure under an administrative protective order, unless the submitting party claims that there is a clear and compelling need to withhold the information from disclosure under an administrative protective order.

(2) Information claimed to be exempt from disclosure under administrative protective order. (i) If the submitting person claims that there is a clear and compelling need to withhold certain information from disclosure under an administrative protective order (see paragraph (a)(1)(ii) of this section), the submitting person must identify the information by enclosing the information within double brackets, and must include a full explanation of the reasons for the claim.

(ii) In an investigation, the submitting person may enclose business proprietary customer names within double brackets (see paragraph (a)(1)(iii) of this section).

(iii) The submitting person may exclude the information in double brackets from the Business Proprietary/APO Version of the submission served on authorized applicants. See § 351.303 for filing and service requirements.

(c) *Public version.* (1) A person filing a submission that contains information for which business proprietary treatment is claimed must file a public version of the submission. The public version must be filed on the first business day after the filing deadline for the business proprietary document (see § 351.303(b)). The public version must contain a summary of the bracketed information in sufficient detail to permit a reasonable understanding of the substance of the information. If the submitting person claims that summarization is not possible, the claim must be accompanied by a full explanation of the reasons supporting that claim. Generally, numerical data will be considered adequately summarized if grouped or presented in terms of indices or figures within 10 percent of the actual figure. If an individual portion of the numerical data is voluminous, at least one percent representative of that portion must be summarized. A submitter should not create a public summary of business proprietary information of another person.

(2) If a submitting party discovers that it has failed to bracket information correctly, the submitter may file a complete, corrected business proprietary document along with the public version (see § 351.303(b)). At the close of business on the day on which the public version of a submission is due under paragraph (c)(2) of this section, however, the bracketing of business proprietary information in the original business proprietary document or, if a corrected version is timely filed, the corrected business proprietary document will become final. Once bracketing has become final, the Secretary will not accept any further corrections to the bracketing of information in a submission, and the Secretary will treat non-bracketed information as public information.

(d) * * *

(1) *In general.* The Secretary will reject a submission that does not meet the requirements of section 777(b) of the Act and this section with a written explanation. The submitting person may take any of the following actions within two business days after receiving the Secretary's explanation:

* * * * *

(iv) Submit other material concerning the subject matter of the rejected information. If the submitting person does not take any of these actions, the Secretary will not consider the rejected submission.

* * * * *

[FR Doc. 2010–18389 Filed 7–27–10; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 882 and 890

[Docket No. FDA–2009–N–0493]

RIN 0910–ZA37

Neurological and Physical Medicine Devices; Designation of Special Controls for Certain Class II Devices and Exemption From Premarket Notification; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until September 7, 2010, the comment period for the proposed rule published in the **Federal Register** of April 5, 2010 (75 FR 17093). The document proposed to amend certain neurological and physical medicine device regulations to establish special controls for these class II devices and to exempt some of these devices from premarket notification requirements. FDA is reopening the comment period to allow further comment and to receive any new information.

DATES: Submit electronic or written comments by September 7, 2010.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2009–N–0493, and/or RIN number 0910–ZA37, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- 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.

Instructions: All submissions received must include the agency name and Docket No. and Regulatory Information Number (RIN) (if a RIN number has been assigned) 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 in 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, 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: Robert J. DeLuca, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G214, Silver Spring, MD 20993–0002, email: *Robert.DeLuca@fda.hhs.gov*, 301–796–6630.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 5, 2010 (75 FR 17093), FDA published a proposed rule to amend certain neurological device and physical medicine device regulations to establish special controls for these class II devices and to exempt some of these devices from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act. Interested persons were given until July 6, 2010, to comment on the proposed rule.

II. Request for Comments

Following publication of the April 5, 2010, proposed rule, FDA received requests to allow interested persons additional time to comment. The requests asserted that the 90-day time period was insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues. The agency has considered the requests and is reopening the comment period until September 7, 2010. The agency believes the additional comment period allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

III. How to Submit 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: July 22, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–18405 Filed 7–27–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

27 CFR Part 646

[Docket No. ATF 22P; AG Order No. 3179–2010]

RIN 1140–AA31

Implementation of the USA PATRIOT Improvement and Reauthorization Act of 2005 Regarding Trafficking in Contraband Cigarettes or Smokeless Tobacco (2006R–1P)

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Justice is proposing to amend the regulations of the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) to implement certain provisions of the USA PATRIOT Improvement and Reauthorization Act of 2005 (enacted March 9, 2006) relating to trafficking in contraband cigarettes or smokeless tobacco. The new law amends the Contraband Cigarette Trafficking Act by: reducing the threshold amount of cigarettes necessary to trigger jurisdiction under the CCTA from a quantity in excess of 60,000 to a quantity in excess of 10,000; extending the provisions of the CCTA to cover contraband smokeless tobacco; imposing reporting requirements on persons, except tribal governments, who engage in delivery sales of more than 10,000 cigarettes or 500 single-unit consumer-sized cans or packages of smokeless tobacco in a single month; requiring that cigarettes and smokeless tobacco seized and forfeited under the CCTA be either used in law enforcement operations or destroyed; and by authorizing state and local governments, and Federal tobacco permittees to bring civil causes of action against violators of the CCTA.

DATES: Written comments must be postmarked and electronic comments must be submitted on or before October 26, 2010. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: Send comments to any of the following addresses—

- James P. Ficaretta, Program Manager, Mailstop 6N–602, Enforcement Programs and Services, Bureau of Alcohol, Tobacco, Firearms, and Explosives, U.S. Department of Justice, 99 New York Avenue, NE., Washington, DC 20226; *Attn: ATF 22P.* Written comments must appear in a minimum 12-point size of type (.17 inches), include your mailing address, be signed, and may be of any length.
- 202–648–9741 (facsimile).
- *http://www.regulations.gov.* Federal eRulemaking portal; follow the instructions for submitting comments.

You may also view an electronic version of this proposed rule at the *http://www.regulations.gov* site.

Comments may also be submitted electronically to ATF to *http://www.regulations.gov* by using the electronic comment form provided on that site. You may also view an electronic version of this proposed rule at the *http://www.regulations.gov site.* Comments submitted electronically must contain your name and mailing address. They must also reference this document docket number, as noted above, and be legible when printed on 8½″ x 11″ paper. ATF will treat comments submitted electronically as originals and it will not acknowledge receipt of comments submitted electronically. Interested parties will not be able to submit comments electronically to ATF via *http://www.regulations.gov* after the comment period closes.

See the Public Participation section at the end of the **SUPPLEMENTARY INFORMATION** section for instructions and requirements for submitting written comments, and for information on how to request a public hearing.

FOR FURTHER INFORMATION CONTACT: James P. Ficaretta; Enforcement Programs and Services; Bureau of Alcohol, Tobacco, Firearms, and Explosives; U.S. Department of Justice;