INTERNATIONAL TRADE COMMISSION

19 CFR Part 220

Rules Relating to the Submission and Consideration of Petitions for Duty Suspensions and Reductions

AGENCY: United States International Trade Commission.

ACTION: Final rule.

SUMMARY: The United States International Trade Commission (Commission) is adopting as a final rule the interim rule published on September 30, 2016. The rule concerns the submission and consideration of petitions for duty suspensions and reductions under the American Manufacturing and Competitiveness Act of 2016.

DATES: *Effective date:* December 26, 2018.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary, telephone (202) 205–2000 or William Gearhart, Esquire, Office of the General Counsel, United States International Trade Commission, telephone (202) 205–3091. Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. Members of the public may obtain general information concerning the Commission by accessing its website at *https://www.usitc gov.*

SUPPLEMENTARY INFORMATION: The preamble below is designed to assist readers in understanding this final rule. This preamble provides background information and a regulatory analysis of the rule.

This rule is being promulgated in accordance with the Administrative Procedure Act (5 U.S.C. 553) (APA), and will be codified in 19 CFR part 220.

Background

Section 335 of the Tariff Act of 1930 (19 U.S.C. 1335) authorizes the Commission to adopt such reasonable procedures, rules and regulations as it deems necessary to carry out its functions and duties. In addition, section 3(b)(5) of the American Manufacturing Competitiveness Act of 2016 (19 U.S.C. 1332 note) (the Act) directs the Commission to prescribe and publish, in the **Federal Register** and on a publicly available internet website of the Commission, procedures to be complied with by members of the public in submitting petitions for duty suspensions and reductions under section 3(b)(1)(A) of the Act.

The Commission is adopting as a final rule, without change, the interim rule published in the **Federal Register** on September 30, 2016 (81 FR 67144) governing the submission and consideration of petitions for duty suspensions and reductions under the Act. In its notice announcing the interim rule, the Commission invited members of the public to file written comments on the rule. The Commission asked members of the public to file such comments no later than November 29, 2016; no written comments were filed.

The principal provisions of the Act relating to the submission and consideration of petitions for duty suspensions and reductions are set out in section 3 of the Act. Section 3 establishes a process for the submission and consideration of petitions for duty suspensions. It also lists the types of information that must be included in a petition, and requires that petitioners submit disclosure forms with respect to such duty suspensions and reductions. Section 3 requires the Commission to publish on its website all the petitions that contain the required information and the related disclosure forms. It also requires that the Commission provide opportunity for members of the public to submit comments to the Commission on the petitions published. Section 3 requires that the Commission submit preliminary and final reports on the petitions that meet the statutory requirements to the House Committee on Ways and Means and Senate Committee on Finance (the Committees), and it sets out the types of information to be included in those reports. Finally, section 3 sets out a timeline, in the form of specific dates or numbers of days, under which the Commission must complete each step in the process, beginning with the filing of petitions and ending with the submission of the Commission's final report.

The American Manufacturing Competitiveness Act provided for two periods during which the Commission would receive and consider petitions and submit reports to the Committees, with the first beginning no later than October 15, 2016, and the second beginning no later than October 15, 2019. The Commission submitted its report to the Committees on petitions received during this first period in August 2017. On September 13, 2018, the President signed the Miscellaneous Tariff Bill Act of 2018 (Pub. L. 115–239), that approved legislation implementing certain temporary duty suspensions and reductions based on the Commission's report. The duty suspensions and reductions became effective on October 13, 2018, and remain in effect through December 31, 2020.

The process under which the Commission received and considered petitions for duty suspensions and reductions was new with the American Manufacturing Competitiveness Act. Previously, the Commission had provided technical assistance to the Committees on duty suspension/reduction bills introduced by Members of Congress under procedures established by the Committees.

Possible Additional Amendments to Part 220

The Commission gained considerable experience in applying the interim rule to petitions submitted and considered with respect to its first report. Based on that experience, the Commission may propose several amendments to this final rule in the near future, with the intent that the amendments be in place before October 15, 2019. Should the Commission propose changes to part 220, the Commission expects to do so by first issuing a notice of proposed rulemaking and request for comments, and after considering those comments, by adopting a final rule.

Regulatory Analysis

The Commission has determined that this final rule does not meet the criteria described in section 3(f) of Executive Order 12866 (58 FR 51735, October 4, 1993) and thus does not constitute a ''significant regulatory action'' for purposes of the Executive Order.

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) is inapplicable to this rulemaking because it is not one for which a notice of proposed rulemaking is required under 5 U.S.C. 553 or any other statute.

This final rule does not contain federalism implications warranting the preparation of a federalism summary impact statement pursuant to Executive Order 13132 (64 FR 43255, August 10, 1999).

No actions are necessary under title II of the Unfunded Mandates Reform Act of 1995, Public Law 104–4 (2 U.S.C. 1531–1538), because the final rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year (adjusted annually for inflation), and will not significantly or uniquely affect small governments.

This final rule does not constitute a ''major'' rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*). Moreover, it is exempt from the reporting requirements of that Act because it contains rules of agency organization, procedure, or

practice that do not substantially affect the rights or obligations of non-agency parties.

The rule does not contain any information collection requirements subject to the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

PART 220—PROCESS FOR CONSIDERATION OF PETITIONS FOR DUTY SUSPENSIONS AND REDUCTIONS

■ Accordingly, the interim rule that was published at 81 FR 67144 on September 30, 2016, is adopted as a final rule without change.

By order of the Commission.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–27768 Filed 12–21–18; 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–1210]

Neurological Devices; Reclassification of Electroconvulsive Therapy Devices; Effective Date of Requirement for Premarket Approval for Electroconvulsive Therapy Devices for Certain Specified Intended Uses

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify the electroconvulsive therapy (ECT) device for use in treating catatonia or a severe major depressive episode (MDE) associated with major depressive disorder (MDD) or bipolar disorder (BPD) in patients age 13 years and older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition, which is a preamendments class III device, into class II (special controls). FDA is also issuing this final order to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the preamendments class III ECT devices for all other uses that are not being reclassified to class II (product code GXC).

DATES: This order is effective on December 26, 2018. See further discussion in section V, Implementation Strategy.

FOR FURTHER INFORMATION CONTACT: Carlos Peña, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2680, Silver Spring, MD 20993, 301–796–6610, *carlos.pena@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Table of Abbreviations/Commonly Used Acronyms in This Document

TABLE OF ABBREVIATIONS AND ACRONYMS

Abbreviation or acronym	What it means
510(k)	Premarket Notification.
2011 Panel	2011 Neurological Devices Panel Meeting.
AACAP	American Academy of Child and Adolescent Psychiatry.
APA	American Psychiatric Association.
BPD	Bipolar Disorder.
CANTAB	Cambridge Neuropsychological Test Automated Battery.
CFR	Code of Federal Regulations.
CGI–I	Clinical Global Impressions-Improvement scale.
ECT	Electroconvulsive Therapy Device.
FDA	Food and Drug Administration.
FDARA	FDA Reauthorization Act of 2017.
FDASIA	Food and Drug Administration Safety and Innovation Act.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FR	Federal Register.
IDE	Investigational Device Exemption.
MAUDE	Manufacturer and User Facility Device Experience.
MDD	Major Depressive Disorder.
MDE	Major Depressive Episode.
MDR	Medical Device Reporting.
M–ECT	Maintenance ECT.
MMSE	Mini Mental State Exam.
OMB	Office of Management and Budget.
PDP	Product Development Protocol.
PMA	Premarket Approval Application.
PRA	Paperwork Reduction Act of 1995.
Ref	Reference
RWD	Real-World Data.
RWE	Real-World Evidence.
SE	Safety and Effectiveness.
U.S.C.	United States Code.
WFSBP	World Federation of Societies of Biological Psychiatry.

II. Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act), establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness (SE). The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices) are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) [1] are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21

[1] ECT devices with intended uses outside the scope of those listed in paragraphs 21 CFR 882.5940(b)(1) and (2) are considered postamendments device, that are subject to classification under section 513(f)(1) of the FD&C Act or, if the relevant requirements are met, under section 513(f)(2) of the FD&C Act.