Dated: March 18, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0493]

Agency Information Collection Activities; Proposed Collection; Comment Request; Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information associated with the criteria and procedures for classifying over-the-counter (OTC) drugs as generally recognized as safe and effective and not misbranded, in accordance with regulations and discussed in the Guidance for Industry ''Time and Extent Applications for Nonprescription Drug Products.''

DATES: Submit either electronic or written comments on the collection of information by May 23, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Additional Criteria and Procedures for Classifying OTC Drugs as Generally Recognized as Safe and Effective and Not Misbranded—21 CFR 330.14 (OMB Control Number 0910–0688)—Extension

In the **Federal Register** of January 23, 2002 (67 FR 3060), we established regulations in § 330.14 (21 CFR 330.14) providing additional criteria and procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded (2002 time and extent application (TEA) final rule). These regulations state that OTC drug products introduced into the U.S. market after the OTC drug review began and OTC drug products without any marketing experience in the United States can be evaluated under the monograph process if the conditions (e.g., active ingredients) meet certain ''time and extent'' criteria outlined in § 330.14(b). The regulations allow a TEA to be submitted to us by any party for our consideration to include new conditions in the OTC drug monograph system. TEAs must provide evidence described in § 330.14(c) demonstrating that the condition is eligible for inclusion in the monograph system. (Section 330.14(d) specifies the number of copies and address for submission of a TEA.) If a condition is found eligible, any interested parties can submit safety and effectiveness information as explained in § 330.14(f). Safety and effectiveness data includes the data and information listed in 21 CFR 330.10(a)(2), a listing of all serious adverse drug experiences that may have occurred, and an official or proposed compendial monograph. We published the Guidance for Industry ''Time and Extent Applications for Nonprescription Drug Products'' in September 2011.

In the **Federal Register** of February 8, 2011 (76 FR 6801), we published a 60-day notice requesting public comment on the proposed collection of information. In that notice, we stated that, based on the number of submissions we had received in the 8 years following publication of the TEA final rule, we expected to receive an average of two TEAs and two submissions of safety and effectiveness data each year. In the same document, we stated our estimate that approximately 1,525 hours are required to prepare a TEA and approximately 2,350 hours to prepare a safety and effectiveness submission. This estimate is based on a comment from a manufacturer that filed two TEAs that was submitted to the Agency in response to the 60-day notice requesting public comment on this proposed collection of information in the **Federal Register** of October 8, 2010, (75 FR 62404). The commenter included, as part of the estimated burden of safety and effectiveness data submission, an estimate to submit environmental data to conduct an environmental assessment, as required by the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 et seq.) (see 21 CFR 25.1), or the application of any categorical exclusion that may be warranted (21 CFR 25.20(f)). Because the information provided in the submission is based on actual experience by a TEA applicant and included an estimated burden to comply with NEPA, we agreed with the submission and adjusted our estimates accordingly. Based on our experience since the February 8, 2011, **Federal Register** notice, we continue to estimate that we will receive two TEAs and two safety and effectiveness submissions each year, and that it will take

approximately 1,525 hours to prepare a TEA and 2,350 hours to prepare a comprehensive safety and effectiveness submission, to include environmental data.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
330.14(c)—Time & Extent Application and (d)[2]—submission of information; confidentiality	2	1	2	1,525	3,050
330.14(f)—Request for data and views and (i)[3]—compendial monograph	2	1	2	2,350	4,700
Total					7,750

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] TEA.
[3] Safety and effectiveness submission, including environmental data in accordance with 21 CFR 25.1.

Dated: March 18, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0217]

Premarket Notification Submissions for Electrosurgical Devices for General Surgery; Draft Guidance for Industry and Food and Drug Administration Staff; 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 ''Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery.'' FDA has developed this guidance document to assist industry in preparing premarket notification (510(k)) submissions for electrosurgical devices intended for use in general surgery. 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 June 23, 2014.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* 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: Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G404, Silver Spring, MD 20993–0002, 301–796–6524.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed this guidance document to assist industry in preparing premarket notification (510(k)) submissions for electrosurgical devices intended for use in general surgery. These devices are designed to cut and/or remove tissue and control bleeding through the use of high frequency electrical current. For the purpose of this guidance, electrosurgical devices may also be called radiofrequency devices or high frequency devices. The scope of this document is limited to the class II, electrosurgical devices and accessories classified under 21 CFR 878.4400, *Electrosurgical cutting and coagulation device and accessories.*

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 the content of premarket notification (510(k)) submissions for electrosurgical devices for general surgery. 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 downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery,'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1835 to identify the guidance you are requesting.

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