

for both types of establishments to benefit from this incentive.

In order to implement a phased-in approach, FDA intends to begin collecting quality metrics data as part of a voluntary phase of the program. The first phase of the quality metrics program outlined in the revised draft guidance would be fully voluntary. After evaluating the results of the voluntary phase of the quality metrics program in 2018, FDA intends to initiate notice and comment rulemaking under existing statutory authority to develop a mandatory quality metrics reporting program.

FDA carefully considered supporting flexible data collection timeframes for the purposes of reporting. In the context of a program that required product-based reporting, such flexibility would be feasible. However, in the context of the voluntary phase of the reporting program, FDA is proposing a common timeframe to facilitate publication of the quality metrics reporters list, and given the need to identify duplicate data if both the product reporting establishment and site reporting establishment submit data.

A Technical Specifications Document entitled "Quality Metrics Technical Conformance Guide, Version 1.0" was published on June 27, 2016 (81 FR 41545). This guide provides technical recommendations for the submission of quality metrics data. It is intended to serve as the technical reference for implementation of the quality metrics program. FDA intends to publish Version 2.0 of the Technical Conformance Guide soon after publication of the revised draft guidance. We anticipate that the electronic submission platform will be available to test in 2017.

Reporting establishments will be able to submit 300 word text comments to provide an explanation of submitted data or report plans for improvement. FDA may refer to the comments if unusual data or trends are identified or as preparation for an onsite inspection. The submission of comments is optional. In the future, FDA may consider establishing a set of codes to standardize the comments.

FDA also revised the draft guidance to address the special complexities for grouping non-application drug products. Defining a "product" for the purpose of grouping non-application drugs for the submission of quality metrics data proved challenging without an application number. Using one segment to group products, such as active pharmaceutical ingredient(s), manufacturing process, minor formulation changes, or stock-keeping

unit, is an imperfect solution. For the purpose of this revised draft guidance, FDA has defined a product family for finished drug products as any combination of National Drug Code (NDC) product code segments where the active pharmaceutical ingredient and dose form is the same (*i.e.*, a product family could be multiple strengths or only a single strength). For APIs, the product family is defined by the NDC product code segment. Our intent is to define product family in a way that was likely consistent with how products are grouped for the Periodic Product Review per 21 CFR 211.180(e) (*e.g.*, Annual Product Review). We expect that this approach will group similar products with similar manufacturing operations together.

There are also special considerations with respect to product quality complaints for OTC products. Manufacturers of OTC products typically receive much more frequent communications from customers than manufacturers of prescription drug products, and the nature of these communications are quite different. The definition of a product quality complaint is intended to cover any possible or actual quality issue, while excluding preferential complaints. We anticipate that our analytics will account for this imbalance in reporting type between prescription and OTC drug products.

III. How To Report Quality Metrics Data to FDA

FDA expects to encourage reporting establishments to submit quality metrics data reports where the data is segmented on a quarterly basis throughout a single calendar year. At present, FDA intends to open the electronic portal in January 2018 to receive voluntary submissions of data. FDA expects to publish a **Federal Register** notice providing instructions on the submission of voluntary reports and specifying the dates that we intend to open the portal, published no fewer than 30 days before the portal is opened (*e.g.*, before December 1, 2017). FDA expects to begin the data analysis once the portal is closed and then publish initial findings and the quality metric reporters list on the FDA Web site.

To reduce discrepancies between site and product reporting, FDA is proposing a defined, uniform reporting period.

In the rare instance that a reporting establishment or covered establishment discovers an error in its submission, an amendment may be made with an associated explanation via email to OPQ-OS-QualityMetrics@fda.hhs.gov.

The amendment process is specified in the Technical Conformance Guide.

IV. Paperwork Reduction Act of 1995

This revised draft guidance contains information collection provisions that 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 collection of some of the information requested in the revised draft guidance is covered under FDA regulations at 21 CFR parts 210 and 211 and approved under OMB control number 0910–0139. In accordance with the PRA, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances. Subject to OMB approval, FDA anticipates that it will begin collecting quality metrics data in January 2018.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov/>.

Dated: November 18, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–28332 Filed 11–23–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Bioequivalence Recommendations for Cyclobenzaprine Hydrochloride; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a revised draft guidance for industry on generic cyclobenzaprine hydrochloride extended release capsules, entitled "Draft Guidance on Cyclobenzaprine Hydrochloride." The recommendations provide specific guidance on the design

of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for cyclobenzaprine hydrochloride extended release capsules.

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 comments 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 January 24, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov/>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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."

Instructions: All submissions received must include the Docket No. FDA-

2007-D-0369 for "Bioequivalence Recommendations for Cyclobenzaprine Hydrochloride; Revised Draft Guidance for Industry; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," will be publicly viewable at <https://www.regulations.gov/> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov/>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY**

INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Xiaoqiu Tang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993-0002, 301-796-5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled "Bioequivalence Recommendations for Specific Products," which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at <http://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Guidances/default.htm>.

As described in that guidance, FDA adopted this process to develop and disseminate product-specific BE recommendations and to provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of revised draft BE recommendations for generic cyclobenzaprine hydrochloride extended release capsules.

FDA initially approved new drug application 021777 for AMRIX (cyclobenzaprine hydrochloride) extended release capsules in February 2007. In August 2008, FDA issued a draft guidance for industry on BE recommendations for generic cyclobenzaprine hydrochloride extended release capsules. We are now issuing a revised draft guidance for industry on BE recommendations for generic cyclobenzaprine hydrochloride extended release capsules ("Draft Guidance on Cyclobenzaprine Hydrochloride").

In June 2016, Teva Pharmaceuticals Industries, Ltd. and its wholly-owned subsidiaries, Teva Pharmaceuticals International GmbH, Teva Pharmaceuticals USA, Inc., Teva Sales and Marketing, Inc., Teva Branded Pharmaceutical Products R&D, Inc., and Cephalon, Inc., submitted a citizen petition requesting that FDA take several actions with respect to ANDAs for cyclobenzaprine hydrochloride extended release oral capsules, including regarding the demonstration of BE for any ANDA referencing AMRIX. FDA has reviewed the issues raised in this citizen petition and is responding to the citizen petition separately in the docket for that citizen

petition (Docket No. FDA-2016-P-1873, available at <https://www.regulations.gov/>).

This revised 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 current thinking of FDA on the design of BE studies to support ANDAs for cyclobenzaprine hydrochloride extended release capsules. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the revised draft guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov/>.

Dated: November 18, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Request for Nominations on the Blood Products Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Blood Products Advisory Committee for the Center for Biologics Evaluation and Research (CBER) notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the Blood Products Advisory Committee. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to

FDA by December 23, 2016. See sections I and II of this document for further details. Concurrently, nomination materials for prospective candidates should be sent to FDA by December 23, 2016.

ADDRESSES: All statements of interest from industry organizations that wish to participate in the selection process of nonvoting industry representative nomination should be sent to Bryan Emery (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's Web site <http://www.fda.gov/AdvisoryCommittees/default.htm>.

FOR FURTHER INFORMATION CONTACT: Bryan Emery, Division of Scientific Advisors and Consultants, CBER, 10903 New Hampshire Ave., Bldg. 71, Rm. 6128, Silver Spring, MD 20993-0002, 240-402-8054, Fax: 301-595-1307, email: bryan.emery@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative(s) to the following advisory committee:

I. CBER Blood Products Advisory Committee

The Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood; products derived from blood and serum or biotechnology intended for use in the diagnosis, prevention, or treatment of human diseases; and, as required, any other product for which FDA has regulatory responsibility. The Committee then advises the Commissioner of Food and Drugs of its findings regarding screening, testing, and labeling of products on clinical and laboratory studies involving such products on the affirmation or revocation of biological products licenses, as well as on the quality and relevance of FDA's research program that provides the scientific support for regulating these agents. The Committee will function at times as a medical device panel under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) Medical Device Amendments of 1976. As such, the Committee: (1)

Recommends classification of devices subject to its review into regulatory categories, (2) recommends the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category, (3) advises on formulation of product development protocols and reviews premarket approval applications for those devices to recommend changes in classification as appropriate, (4) recommends exemption of certain devices from the application of portions of the FD&C Act, (5) advises on the necessity to ban a device, and (6) responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).