pharmacists) are not clearly communicated in REMS documents. Stakeholders have reported spending excessive time trying to locate, understand, and comply with REMS requirements.

To address the stakeholders' feedback, FDA is revising the 2009 draft guidance on the format and content of a REMS to include information to assist applicants in drafting clear, informative, and standardized REMS documents. This revised draft guidance provides updated recommendations on the format and content of a REMS document and supersedes the 2009 draft guidance. Additional and more detailed information is provided in the template appended to this guidance.

The new format of the REMS document, as described in this revised draft guidance and appended template, contains substantially the same content as described in the 2009 draft guidance; however, the information has been reorganized. In the old format, the REMS requirements were organized by the elements described in the statute. In the new format, requirements are organized to describe who is responsible for implementing the requirement, when the requirement is to be implemented, what the required action is, and with what REMS material(s). Additionally, the new format supports submission of REMS documents in Structured Product Labeling (SPL) format.

Certain information included in the 2009 draft guidance has been revised and included in other guidances subsequently published and therefore has been omitted from this revised draft guidance. For example:

- Information on how FDA determines when a REMS is necessary to ensure that the benefits of a drug outweigh its risks can be found in the draft guidance for industry, ''FDA's Application of Statutory Factors in Determining When a REMS Is Necessary'' (at: *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm521504.pdf*).
- Information on REMS modifications can be found in the guidance for industry, ''Risk Evaluation and Mitigation Strategies: Modifications and Revisions'' (at: *https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm441226.pdf*).

This revised guidance and appended template are being reissued in draft form to enable the public to review and comment before finalization.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on the format and content of a REMS document. 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. This guidance is not subject to Executive Order 12866.

II. The 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 information in the guidance was approved under OMB control numbers 0910–0001 and 0910–0338.

III. Electronic Access

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

Dated: October 5, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–22050 Filed 10–11–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5868]

Requests for Reconsideration at the Division Level Under the Generic Drug User Fee Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Requests for Reconsideration at the Division Level Under GDUFA.'' This guidance provides recommendations for industry on the procedures for resolving scientific and/or regulatory issues or matters between FDA and applicants of abbreviated new drug applications (ANDAs) that wish to pursue a request for reconsideration within the review discipline at the division level or original signatory authority. This guidance also provides information for applicants to consider before pursuing a request for reconsideration, procedures for submitting a request for reconsideration, and the Agency's process for responding to those requests.

DATES: Submit either electronic or written comments on the draft guidance by December 11, 2017 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–

2017–D–5868 for ''Requests for Reconsideration at the Division Level Under GDUFA; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 Dockets Management Staff. 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: *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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: Lisa Bercu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1611, Silver Spring, MD 20993–0002, 240–402–6902.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Requests for Reconsideration at the Division Level Under GDUFA.'' This guidance provides recommendations for industry on the procedures for resolving scientific and/or regulatory issues or matters between FDA and applicants of ANDAs that wish to pursue a request for reconsideration within the review discipline at the division level or original signatory authority. In accordance with ''GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018–2022'' (GDUFA II Goals Letter or GDUFA II Commitment Letter; *https://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM525234.pdf*), FDA agreed to certain review goals and procedures for the review of requests for reconsideration received on or after October 1, 2017.[1]

As agreed to by FDA and industry in the GDUFA II Commitment Letter, applicants may pursue a request for reconsideration within the review discipline at the division level. In addition, if an applicant requests a teleconference as part of its request to reclassify a major amendment or standard review status, FDA will schedule and conduct the teleconference and decide 90 percent of such reclassification requests within 30 days of the date of FDA's receipt of the request for a teleconference. As stated in the GDUFA II Commitment Letter, this goal only applies when the applicant accepts the first scheduled teleconference date offered by FDA. This guidance provides additional details and recommendations concerning considerations for applicants before pursuing a request for reconsideration and procedures for submitting a request for reconsideration and the Agency's process for responding to those requests.

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 current thinking of FDA on ''Requests for Reconsideration at the Division Level Under GDUFA.'' 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. This guidance is not subject to Executive Order 12866.

[1] The FDA Reauthorization Act of 2017 (Pub. L. 115–52) included the reauthorization of generic user fees as Title III, Generic Drug User Amendments of 2017 (GDUFA II).

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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.

Applications for FDA Approval To Market a New Drug

OMB Control Number 0910–0001—Revision

The information collection request supports the Agency's draft guidance entitled, ''Requests for Reconsideration at the Division Level Under GDUFA.'' As discussed in section I of this notice, this guidance provides information to respondents regarding procedures for

submitting requests for reconsideration, including details on the content and format of the submission. Respondents to the collection of information are applicants of ANDAs. Based on available data with regard to similar information collections, FDA's Center for Drug Evaluation and Research will receive approximately 150 requests for reconsideration annually from 75 respondents. Because we estimate it will take 5 hours to prepare a request for reconsideration, we estimate it will take an average of 750 total hours annually for respondents to prepare and submit requests for reconsideration. The burden of the information collection, therefore, is estimated as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance recommendation	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Section IV: Procedures for Submitting and Responding to a Request for Reconsideration	75	2	150	5	750

[1] There are no capital or operating and maintenance costs associated with the collection of information.

III. Electronic Access

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

Dated: October 5, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–22049 Filed 10–11–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0424]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Temporary Marketing Permit Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 13, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0133. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7729, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Temporary Marketing Permit Applications—21 CFR 130.17(c) and (i)

OMB Control Number 0910–0133—Extension

This information collection supports Agency regulations. Specifically, section 401 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 341) directs FDA to issue regulations establishing definitions and standards of identity for food ''whenever . . . such action will promote honesty and fair dealing in the interest of consumers . . . .'' Under section 403(g) of the FD&C Act (21 U.S.C. 343(g)), a food that is subject to a definition and standard of identity prescribed by regulation is misbranded if it does not conform to such definition and standard of identity. Section 130.17 (21 CFR 130.17) provides for the issuance by FDA of temporary marketing permits that enable the food industry to test consumer acceptance and measure the technological and commercial feasibility in interstate commerce of experimental packs of food that deviate from applicable definitions and standards of identity. Section 130.17(c) enables the Agency to monitor the manufacture, labeling, and distribution of experimental packs of food that deviate from applicable definitions and standards of identity. The information so obtained can be used in support of a petition to establish or amend the applicable definition or standard of identity to provide for the variations. Section 130.17(i) specifies the information that a firm must submit to FDA to obtain an extension of a temporary marketing permit.

In the **Federal Register** of June 15, 2017 (82 FR 27489), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received.

We therefore estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
130.17(c)—Request for temporary marketing permit	13	2	26	25	650
130.17(i)—Request to extend marketing permit	1	2	2	2	4
Total					654

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.