DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1064]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Petitions for Exemption From Preemption

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 December 6, 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 0910–0277. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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.

State Petitions for Exemption From Preemption

OMB Control Number 0910–0277—Extension

Under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343–1(b)), States may petition FDA for exemption from Federal preemption of State food labeling and standard-of-identity requirements. Section 100.1(d) (21 CFR 100.1(d)) sets forth the information a State is required to submit in such a petition. The information required under § 100.1(d) enables FDA to determine whether the State food labeling or standard-of-identity requirement satisfies the criteria of section 403A(b) of the FD&C Act for granting exemption from Federal preemption.

In the **Federal Register** of June 15, 2017 (82 FR 27491), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received no comments.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR 100.1(d)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Form of petition	1	1	1	40	40

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

The reporting burden for § 100.1(d) is minimal because petitions for exemption from preemption are seldom submitted by States. In the last 3 years, we have received one new petition for exemption from preemption; therefore, we estimate that one or fewer petitions will be submitted annually.

Dated: November 1, 2017.

Anna K. Abram,

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

[FR Doc. 2017–24106 Filed 11–3–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–3101]

Abbreviated New Drug Applications: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications (Pre-Submission Facility Correspondence); 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 revised draft guidance for industry entitled ''ANDAs: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications (Pre-Submission Facility Correspondence).'' FDA is revising the draft guidance because, after issuance of the original draft guidance, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) was amended by the FDA Reauthorization Act of 2017, which resulted in changes to the pre-submission of facility information. Pre-submitting facility information enables the Agency to determine whether inspection of a facility is necessary and, if so, to begin inspection planning in advance of an abbreviated new drug application (ANDA) receipt.

DATES: Submit either electronic or written comments on the draft guidance by February 5, 2018 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 concerning the collection of information proposed in the draft guidance by January 5, 2018.

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–3101 for ''ANDAs: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications (Pre-Submission Facility Correspondence).'' 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: Nikhil Thakur, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 4161, Silver Spring, MD 20993, 301–796–5536.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''ANDAs: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications (Pre-Submission Facility Correspondence).'' The first draft of this document, entitled ''ANDAs: Pre-Submission Facility Correspondence Associated with Priority Submissions,'' was issued pursuant to 21 CFR 10.115 in June 2017. The docket number has not changed since the first draft of this document was issued, and it is not necessary to resubmit comments already submitted to the docket. The Agency will consider comments submitted with respect to the first draft of this document in finalizing the revised document.

The Agency is issuing this revised draft guidance to describe the process through which prospective generic drug applicants submit facility information in advance of an original ANDA, prior approval supplement (PAS), PAS amendment, or ANDA amendment (hereafter collectively referred to as ANDA). FDA is revising the draft guidance because, after issuance of the original draft guidance, section 505(j)(11) of the FD&C Act (21 U.S.C. 355(j)(11)) as added by section 801 of the FDA Reauthorization Act of 2017 (FDARA) resulted in changes to the pre-submission of facility information.

In 2016 and 2017, FDA, regulated industry, and public stakeholders conducted negotiations concerning reauthorization of the Generic Drug User Fee Amendments (GDUFA II). A chief product of these congressionally mandated discussions was the ''GDUFA Reauthorization Performance Goals and Program Enhancements, FYs 2018–2022'' (GDUFA II Commitment Letter) available at: *https://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf.* Together, the Generic Drug User Fee Amendments of 2017 and the GDUFA II Commitment Letter describe FDA's performance goals, as well as changes and improvements to the user fee program.

On August 18, 2017, FDARA, which reauthorized the Generic Drug User Fee Amendments (Title III) as well as other provisions related to generic drugs (Title VIII), was signed into law. In particular, section 801 of the FDARA added section 505(j)(11) to the FD&C Act to address priority review of generic drugs. One of the enhancements specified in both Title VIII, section 801 of FDARA, and the GDUFA II Commitment Letter is a mechanism to enable a shorter review goal (priority review goal) for certain priority original ANDAs, PASs, PAS amendments, and ANDA amendments through the pre-submission of facility information, including sections of the ANDA determined to be relevant by FDA. Specifically, this guidance describes:

• The content and format of the facility information that should be submitted to enable FDA's assessment of facilities listed in the pre-submission.

• Timeframes for pre-submitting sections of the ANDA containing complete, accurate information, and the intersection of these timeframes with submission of the ANDA.
• The possible outcomes of the Agency's assessment of pre-submitted ANDA sections containing facility information.
• When and how the Agency notifies an applicant about the status of the pre-submitted ANDA sections containing facility information.

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 ANDAs: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications (Pre-Submission Facility Correspondence). 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. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing the proposed collection of information set forth in this notice of availability that would result from the pre-submission of facility information.

With respect to the following collection of information, FDA invites comment 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.

Title: Draft Guidance for Industry on ANDAs: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications (Pre-Submission Facility Correspondence).

Description: As described in the draft guidance, section 505(j)(11) of the FD&C Act was added by section 801 of FDARA. Pre-submitting facility information enables the Agency to determine whether inspection of a facility is necessary and, if so, to begin inspection planning in advance of ANDA receipt.

This draft guidance document refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. Existing regulations at 21 CFR 314.94 provide the content and format of an ANDA, and consistent with GDUFA II, this draft guidance describes the relevant sections of an ANDA that should be submitted as part of the pre-submission of facility information. The information collections associated with the submission of these ANDA sections are approved under OMB control number 0910–0001.

There are information collections proposed in the draft guidance that are not already addressed under the approved control numbers covering ANDA submissions. Section IV of the draft guidance describes the information that should be included in the pre-submission of facility information to enable FDA's facility assessment:

A. The planned ANDA pre-assigned number to be submitted with the pre-submission, which the applicant must request from FDA before submitting the pre-submission;

B. Cover letter accompanying the pre-submission, which includes a statement of justification for the expedited review request, a statement of inspection readiness, a statement identifying the Reference Listed Drug, and the anticipated date of the applicant's ANDA submission; and

C. Certification statement to be submitted with the applicant's ANDA stating either that the applicant has made no changes to the pre-submitted facility information, or that the only change was made to exclude a facility as described in 505(j)(11)(B) of the FD&C Act. (Changes other than those permitted under 505(j)(11)(B) of the FD&C Act should be identified in the ANDA cover letter. The applicant will also need to confirm the accuracy of the information provided in the Form FDA 356h submitted with the ANDA, and update accordingly.)

Section VI of the draft guidance describes the format used to submit the pre-submission of facility information, which is the electronic Common Technical Document (eCTD) format. Further, as explained in section V of the draft guidance, the pre-submission must be submitted not later than 60 days prior to the planned ANDA submission.

We estimate that a total of approximately 220 applicants (''number of respondents'' in table 1) will submit annually approximately 275 pre-submissions as described above and in the draft guidance (''total annual responses'' in table 1). We estimate that preparing and submitting the portion of each pre-submission that is not already addressed under approved control numbers covering ANDA submissions will take approximately 1.1 hours (''average burden per response'' in table 1). This includes time spent preparing and submitting a cover letter accompanying the pre-submission of facility information. We estimate that approximately 10 percent of applicants will submit statements notifying the Agency that the applicant has decided not to submit an ANDA, and we have incorporated the estimated time to prepare and submit such a statement in table 1.

We estimate that approximately 198 applicants will submit annually approximately 248 certifications (''total annual responses'' in table 1) verifying either that the applicant has made no changes to the pre-submitted facility information, or that the only change was made to exclude a facility as described in 505(j)(11)(B) of the FD&C Act. We estimate that preparing and submitting each certification will take approximately 4 hours (''average burden per response'' in table 1).

We base our estimates for the number of applicants and the number of pre-submissions on information from our database of annual ANDA submissions, on the criteria set forth in the Agency's Manual of Policies and Procedures 5240.3, *Prioritization of the Review of Original ANDAs, Amendments, and Supplements* (available at: *https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf*), and the number of ''priority'' submissions. Our estimate of the time applicants would need to prepare and submit the portions of each pre-submission not already addressed under approved control numbers covering

ANDA submissions, as well as the pre-submission certification statement (referenced in table 1), takes into consideration that much of this content is related to information already gathered for the ANDA submission. We invite comments on these estimates.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pre-Submission of Facility Information	220	1.25	275	1.1	303
Certification statement submitted with the ANDA	198	1.25	248	4	990

[1] There are no capital costs or operating and maintenance costs associated with this 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 31, 2017.

Anna K. Abram,

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

[FR Doc. 2017–24099 Filed 11–3–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2010–N–0258; FDA–2010–N–0623; FDA–2007–N–0383; FDA–2009–N–0360; FDA–2016–N–4620; FDA–2013–N–1496; FDA–2007–N–0220; FDA–2017–N–1848; FDA–2017–N–1066; FDA–2015–D–3327; FDA–2011–D–0689]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Submission of Petitions: Food Additive, Color Additive (Including Labeling), Submission to Information to a Master File in Support of Petitions; and Electronic Submission Using FDA 3053	0910–0016	9/30/2020
Voluntary Cosmetic Registration Program	0910–0027	9/30/2020
Radioactive Drug Research Committees	0910–0053	9/30/2020
FDA Safety Communication Readership Survey	0910–0341	9/30/2020
Medical Devices; Reports for Corrections and Removals	0910–0359	9/30/2020
Generic FDA Rapid Response Surveys	0910–0500	9/30/2020
Guidance for Industry: Pharmacogenomic Data Submissions	0910–0557	9/30/2020
Cosmetic Labeling Regulations	0910–0599	9/30/2020
Annual Reporting for Custom Device Exemption	0910–0767	9/30/2020
GFI: E6(R2) Good Clinical Practice; International Council for Harmonisation	0910–0843	9/30/2020
DeNovo Classification Process (Evaluation of Automatic Class II Designation)	0910–0844	9/30/2020

Dated: November 1, 2017.

Anna K. Abram,

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

[FR Doc. 2017–24121 Filed 11–3–17; 8:45 am]

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