DocumentsRegulatoryInformation/AcidifiedLACF/ucm309376.htm.

2. Form FDA 2541. Food Process Filing for All Methods Except Low-Acid Aseptic. Available at *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM076778.pdf.*
3. Form 2541d. Food Process Filing for Low-Acid Retorted Method. Available at *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM465591.pdf.*
4. Form 2541e. Food Process Filing for Acidified Method. Available at *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM465593.pdf.*
5. Form 2541f. Food Process Filing for Water Activity/Formulation Control Method. Available at *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM465595.pdf.*
6. Form 2541g. Food Process Filing for Low-Acid Aseptic Systems. Available at *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM465598.pdf.*

Dated: June 14, 2017.

Anna K. Abram,

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

[FR Doc. 2017–12783 Filed 6–19–17; 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Abbreviated New Drug Applications: Pre-Submission Facility Correspondence Associated with Priority Submissions; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''ANDAs: Pre-Submission Facility Correspondence Associated with Priority Submissions.'' The Pre-Submission Facility Correspondence (PFC) process was identified as part of the performance goals and program enhancements for the Generic Drug User Fee Amendments reauthorization for Fiscal Years 2018–2022 (GDUFA II). A complete and accurate PFC allows the Agency to begin the facility assessment process in advance of the planned abbreviated new drug application (ANDA) submission. This draft guidance describes PFC content and format, as well as the Agency's approach to assessing this information.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 18, 2017. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by September 18, 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):* 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 Facility Correspondence Associated with Priority Submissions.'' 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.

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. 4164, Silver Spring, MD 20993, 301–796–5536.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''ANDAs: Pre-Submission Facility Correspondence Associated with Priority Submissions.'' As one of the enhancements specified in the GDUFA II commitment letter, the PFC is a mechanism to achieve expedited review of priority ANDAs, prior approval supplements (PASs), and their amendments (collectively ANDAs). Under the performance goals and program enhancements for GDUFA II, FDA agreed to a shorter goal date for action on a priority generic drug submission if:

- A complete and accurate PFC is submitted to FDA 2 months ahead of the planned ANDA submission, and
- facility information remains unchanged in the ANDA.

A complete and accurate PFC allows the Agency to begin the facility assessment process in advance of the planned ANDA submission. This critical 2-month lead time provides the Agency the opportunity to determine whether facility inspections will be needed, and, when they are, to initiate inspection planning earlier in the review of the ANDA, enabling FDA to meet the shorter review timeframe.

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 Facility Correspondence Associated with Priority Submissions.'' 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. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501–3520) (the PRA), 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 submission of PFCs.

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 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 Facility Correspondence Associated with Priority Submissions.

Description: As described in the draft guidance, the GDUFA II commitments included an agreement to establish a mechanism to facilitate a shortened GDUFA goal date for ANDAs, PASs, and their amendments that have been designated as a ''Priority'' by FDA. For planned ANDAs that successfully meet FDA's priority review criteria, applicants may submit a PFC as a mechanism to facilitate evaluation of facilities associated with a planned ANDA.

Section IV of the draft guidance describes the information that should be submitted in the PFC to enable FDA's facility assessment:

A. General information, including the planned ANDA pre-assigned number (which the applicant must request from FDA before submitting the PFC), PFC submission date, and the applicant's identifying information;

B. statement of ANDA eligibility for priority review;

C. manufacturing process and testing facility information; and

D. bioequivalence summary and site/organization information.

The Appendix of the draft guidance describes the format that should be used to submit the PFC, including a standardized format for administrative information related to manufacturing process and testing sites, and summary tables for bioequivalence sites and organizations and for bioavailability studies.

The PFC should be submitted in the PDF file format through the FDA electronic submissions gateway, and, as explained in the draft guidance, should be submitted 2 or 3 months ahead of the planned ANDA submission.

We estimate that a total of approximately 125 applicants ''number of respondents'' in table 1) will submit annually approximately 275 PFCs as described in the draft guidance (''total annual responses'' in table 1). We estimate that preparing and submitting each PFC as described in the draft guidance will take approximately 32 hours ''hours per response'' in table 1). We base our estimates for the number of applicants and the number of PFCs on information from our database of annual ANDA submissions, and on the criteria set forth in the FDA Center for Drug Evaluation's Manual of Policies and Procedures 5240.3 and the number of ''priority'' submissions. Our estimate of the time applicants would need to prepare and submit each PFC takes into consideration that much of the PFC includes information already gathered for the ANDA submission. Thus, the burden estimate for the submission of the PFC does not double-count the burden of gathering information that is accounted for under OMB control number 0910–0001, under which OMB has approved the submission of ANDAs and related amendments, supplements, and other information required under Subpart C of Part 314 in Title 21 of the CFR.

We invite comments on these estimates.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	No. of respondents	No. of responses per respondent	Total annual responses	Hours per response	Total hours
PFC	125	2.20	275	32	8,800

[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: June 15, 2017.

Anna K. Abram,

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

[FR Doc. 2017–12836 Filed 6–19–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1496]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Rapid Response Surveys (Generic Clearance)

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 July 20, 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 0910–0500. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

FDA Rapid Response Surveys (Generic Collection)

OMB Control Number 0910–0500—Extension

Section 505 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355) requires that important safety information relating to all human prescription drug products be made available to FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the FD&C Act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the FD&C Act. Under section 519 of the FD&C Act (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device-related deaths, serious injuries, and malfunctions to FDA; to require user facilities to report device-related deaths directly to FDA and to manufacturers; and to report serious injuries to the manufacturer. Section 522 of the FD&C Act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the FD&C Act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health or gross deception of the consumer. Section 1003(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)) authorizes the Commissioner of Food and Drugs to implement general powers (including conducting research) to carry out effectively the mission of FDA. These sections of the FD&C Act enable FDA to enhance consumer protection from risks associated with medical products usage that are not foreseen or apparent during the premarket notification and review process. FDA's regulations governing application for Agency approval to market a new drug (21 CFR part 314) and regulations governing biological products (21 CFR part 600) implement these statutory provisions. Currently, FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch reporting systems using FDA Forms 3500 and 3500A (OMB control number 0910–0291) and the vaccine adverse event reporting system.

FDA is seeking OMB clearance to collect vital information via a series of rapid response surveys. Participation in these surveys will be voluntary. This request covers rapid response surveys for community based health care professionals, general type medical facilities, specialized medical facilities (those known for cardiac surgery, obstetrics/gynecology services, pediatric services, etc.), other health care professionals, patients, consumers, and risk managers working in medical facilities. FDA will use the information gathered from these surveys to quickly obtain vital information about medical product risks and interventions to reduce risks so the Agency may take appropriate public health or regulatory action including dissemination of this information as necessary and appropriate.

FDA projects 6 emergency risk related surveys per year with a sample of between 50 and 10,000 respondents per survey. FDA also projects a response time of 0.5 hour per response. These estimates are based on the maximum sample size per questionnaire that FDA may be able to obtain by working with health care professional organizations. The annual number of surveys was determined by the maximum number of surveys per year FDA has ever conducted under this collection.

In the **Federal Register** of January 13, 2017 (82 FR 4354), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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