

the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product EMPLICITI (elotuzumab). EMPLICITI is indicated in

combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received one to three prior therapies. Subsequent to this approval, the USPTO received a patent term restoration application for EMPLICITI (U.S. Patent No. 7,709,610) from AbbVie Biotherapeutics, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 12, 2016, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of EMPLICITI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for EMPLICITI is 3,400 days. Of this time, 3,245 days occurred during the testing phase of the regulatory review period, while 155 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* August 11, 2006. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 11, 2006.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* June 29, 2015. FDA has verified the applicant's claim that the biologics license application (BLA) for EMPLICITI (BLA 761035) was initially submitted on June 29, 2015.

3. *The date the application was approved:* November 30, 2015. FDA has verified the applicant's claim that BLA 761035 was approved on November 30, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,095 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination

(see **DATES**). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: December 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-00108 Filed 1-6-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-4508]

Generic Drug User Fee Amendments II Program Fee: List of Abbreviated New Drug Application Sponsors and Application Numbers; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA) is seeking information and public comment, in anticipation of the passage of Generic Drug User Fee Amendments reauthorization (GDUFA II), relevant to FDA's planned approach for administering generic drug program fees under that legislation for fiscal year (FY) 2018. This includes requests for comment and information regarding FDA's initial inventory of approved abbreviated new drug application sponsors and application numbers. The information gathered from public comments will assist FDA in accurately assessing FY 2018 GDUFA program fees in a timely manner.

DATES: Submit written or electronic comments and information by March 10, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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-2016-N-4508 for "Generic Drug User Fee Amendments II Program Fee: List of Abbreviated New Drug Application Sponsors and Application Numbers; Request for Information and Comment." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://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 <http://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.fda.gov/regulatoryinformation/dockets/default.htm>.

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

FOR FURTHER INFORMATION CONTACT: Kristan Callahan, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Silver Spring, MD 20993, 301-796-7900, CDERCollections@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In anticipation of the enactment and implementation of GDUFA II, FDA has begun taking steps to ensure efficient administration of GDUFA for FY 2018. It is projected that the GDUFA II legislation will include an annual program fee for which holders of approved abbreviated new drug applications (ANDAs) will be responsible.

Under GDUFA II, it is anticipated that affiliated companies will be grouped together and counted as a single entity for purposes of assessing the program fee. The proposed legislation defines the

term "affiliate" in the same way it was defined in GDUFA. An "affiliate" is defined as a business entity that has a relationship with a second business entity if, directly or indirectly, one business entity controls, or has the power to control, the other business entity; or a third party controls, or has the power to control, both of the business entities. As set forth in the proposed legislation, the program fee will be allocated among three tiers of application holders:

- Large (companies with 20 or more approved ANDAs);
- Medium (companies with between 6 and 19 approved ANDAs); and,
- Small (companies with 5 or fewer approved ANDAs).

To assess program fees in an accurate and timely manner if these provisions are enacted, FDA seeks to identify how many approved ANDAs belong to each application holder, and which application holders are affiliates for purposes of assessing GDUFA II program fees. In furtherance of this effort, FDA requests comments and information regarding FDA's initial inventory of approved ANDA sponsors and application numbers. The current spreadsheet containing this initial inventory and instructions on how to use it are available at <http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm>.

II. Request for Information and Comment

FDA is seeking information and public comment, in anticipation of the passage of GDUFA II, relevant to FDA's planned approach for administering generic drug program fees under that legislation for FY 2018. The information gathered from public comments will assist FDA in accurately assessing FY 2018 GDUFA Program Fees in a timely manner. Interested persons are invited to comment, in general, on any aspect of FDA's planned approach for administering these generic drug program fees under GDUFA II. FDA is particularly interested in comments and information addressing the accuracy and completeness of the information in the previously mentioned spreadsheet containing FDA's initial inventory of approved ANDA sponsors and application numbers. In addition, FDA is interested in any information that could be relevant to determining whether two or more companies that are currently listed separately in that spreadsheet should be considered to be affiliated for purposes of assessing the anticipated program fee. As a general matter, FDA does not consider affiliates

to be confidential commercial information.

After receiving feedback and comments on the spreadsheet, FDA anticipates publishing a **Federal Register** notice and making available a revised spreadsheet that will incorporate information received in the comments on this notice. FDA plans to seek comment on the revised spreadsheet before compiling the final information regarding affiliated entities that will be used as the basis for determining and assessing FY 2018 program fees in the event that GDUFA II is enacted.

Dated: January 3, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-00081 Filed 1-6-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Advanced Education Nursing Traineeship (AENT) Program Specific Data Collection Forms

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than February 8, 2017.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443-1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Advanced Education Nursing Traineeship (AENT) Program Specific Data Collection Forms for Use with the New Advanced Nursing Education Workforce (ANEW) Program.

OMB No. 0915-0375—Revision

Abstract: The Advanced Nursing Education Workforce (ANEW) Program is a new program that incorporates elements of HRSA’s Advanced Education Nursing Traineeship (AENT) and Advanced Nursing Education (ANE) programs. The current OMB approved Program Specific Data Collection Forms for the former AENT Program will be simplified and used for the ANEW program. HRSA provides advanced education nursing grants to educational institutions to increase the numbers of advanced education nurses through the ANEW Program. The ANEW Program is authorized by Title VIII, Section 811 of the Public Health Service Act (42 U.S.C. 296j). This renewal with revision request includes the Project Abstract, Program Narrative, Attachments, and Tables. The proposed ANEW Tables are very similar to the previous AENT Tables and include information on program participants such as the projected number of enrollees/trainees receiving traineeship support; projected number of graduates receiving traineeship support for the previous fiscal year; the types of programs they are enrolling into and/or from which enrollees/trainees are graduating, and the distribution of primary care nurse practitioners (NP), primary care clinical nurse specialists (CNS); and nurse-midwives who plan to practice in rural and underserved settings. To reduce the reporting burden for applicants, HRSA simplified the Tables to focus on the types of providers and practice settings that are included in the statute in order to determine whether applicants qualify for the preference or special consideration in making awards for this program.

Need and Proposed Use of the Information: HRSA will use this information in determining the eligibility for the statutory funding preference and special consideration, and to succinctly capture data for the number of projected students for subsequent years in the project period.

Likely Respondents: Likely respondents are potential applicants for the ANEW program. Eligible applicants for the ANEW program include entities that provide registered nurses with primary care NP, primary CNS, and nurse-midwife education. Such programs may include accredited schools of nursing, nursing centers, academic health centers, state or local governments, and other public or private nonprofit entities authorized by the Secretary of HHS to confer degrees to registered nurses for primary care NP, primary care CNS, or nurse-midwife education. Federally recognized Indian Tribal Government and Native American Organizations as well as faith-based or community-based organizations may apply if they are otherwise eligible.

Eligible state government entities include the 50 states, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, American Samoa, the U.S. Virgin Islands, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total estimated annualized burden hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
ANEW Application including the ANEW Program Specific Tables and Attachments	236	1	236	7	1,652