

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA-2017-D-6209]
Assessing User Fees Under the Biosimilar User Fee Amendments of 2017; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Assessing User Fees Under the Biosimilar User Fee Amendments of 2017.” This draft guidance concerns FDA’s implementation of the Biosimilar User Fee Amendments of 2017 (BsUFA II) and certain intended changes in policies and procedures surrounding its application.

DATES: Submit either electronic or written comments on the draft guidance by January 16, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-6209 for “Assessing User Fees Under the Biosimilar User Fee Amendments of 2017.” 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 and 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; or to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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: Beena Alex, Division of User Fee Management and Budget Formulation, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Rm. 2185, Silver Spring, MD 20993, 301-796-7900, CDERCollections@fda.hhs.gov; or to Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:
I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Assessing User Fees Under the Biosimilar User Fee Amendments of 2017.” This draft guidance concerns the implementation of BsUFA II, including an explanation about the new fee structure and types of fees for which entities are responsible. BsUFA II extends FDA’s authority to collect user fees from fiscal year 2018 to 2022 and introduces a number of technical revisions that affect what fees are collected and how fees are collected. Fees authorized by this legislation help fund the process for the review of biosimilar biological product applications and have played an important role in expediting the review and approval process.

BsUFA II authorizes biosimilar biological product development

program fees (BPD fees), biosimilar biological product application fees, and biosimilar biological product program fees. This draft guidance describes when these fees are incurred and the process by which applicants can submit payments. The draft guidance also provides information on consequences of failing to pay BsUFA II fees and the processes for submitting reconsideration and appeal 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 assessing user fees under BsUFA II. 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 notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this document, 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.

Assessing User Fees Under the Biosimilar User Fee Amendments of 2017: Draft Guidance for Industry

OMB Control Number 0910—NEW

This information collection supports "Assessing User Fees Under the

Biosimilar User Fee Amendments of 2017: Draft Guidance for Industry." The Federal Food, Drug, and Cosmetic Act as amended by the Biosimilar User Fee Act of 2012 and recently renewed in 2017 (BsUFA II) under the FDA Reauthorization Act of 2017, authorizes FDA to assess and collect user fees from companies that produce biosimilar biological products in conjunction with the review of biosimilar biological product applications. The draft guidance includes processing and policies for the initial and the annual BPD fees; the BPD discontinuation process requirements and BPD reactivation fees; process and policies for biosimilar biological product application fees including exceptions to the application fees and refund of fees; process and policies for the small business waiver of the biosimilar application fee; and implementation of the biosimilar biological product program fee.

The burdens associated with requesting a small business waiver of BsUFA fees and the associated burdens for new activities as noted in the draft guidance are listed in table 1.

FDA estimates the annual burden of these new collections of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Request for discontinuation from BPD program	2	1	2	1	2
Request to move products to discontinued section of the biosimilar list	5	1	5	.5	2.5
Small business waiver of the BsUFA application fee	1	1	1	16	16
—Reconsiderations	1	1	1	24	24
—Appeals	1	1	1	12	12
Annual Fee Determination Survey	35	1	35	1	35
Annual BsUFA Fees Correspondence	35	1	35	2	70
Total					161.5

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

This draft guidance also refers to previously approved collections of information found in FDA forms developed to support its user fee program. Specifically, the draft guidance refers to Form FDA 3792, Form FDA 3913, and Form FDA 3971, which have been approved under OMB control numbers 0910–0718, 0910–0805, and 0910–0693, respectively. The draft guidance also refers to previously

approved collections of information found in FDA regulations. The collections of information in 21 CFR part 312 are currently approved under OMB control number 0910–0014; the collections of information regarding new drug applications and biologics license applications are approved under OMB control numbers 0910–0001 and 0910–0338, respectively.

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: November 13, 2017.

Anna K. Abram,

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

[FR Doc. 2017-24831 Filed 11-15-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1981-N-0245 (Formerly 81N-0080)]

Mepergan Fortis Capsules; Final Decision on Proposal To Refuse Approval of Supplemental New Drug Application; Availability of Final Decision

AGENCY: Food and Drug Administration; HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing that the Initial Decision of the Administrative Law Judge (ALJ), to refuse approval of the supplemental new drug application (sNDA) for Mepergan Fortis Capsules (MFC) (meperidine HCl, promethazine HCl), is the final decision of the Commissioner by operation of law. In the Initial Decision, the ALJ found that MFC had not been shown to be supported by substantial evidence consisting of adequate and well-controlled studies to be effective for sedation and analgesia in patients with concurrent moderate pain and apprehension, such as postoperative and post-trauma patients with those symptoms; that the drug did not satisfy the combination drug policy; and that it is a “new drug.” The sNDA applicant filed exceptions to the ALJ’s Initial Decision. FDA recently requested that the current owner of the sNDA application affirm its desire to pursue the appeal of the ALJ’s Initial Decision; however, the applicant did not affirm its desire to pursue the appeal within the specified timeframe. Accordingly, FDA now deems those exceptions as withdrawn. Consequently, the proceeding is in the same procedural position as if no exceptions to the ALJ’s Initial Decision had been filed; therefore, the ALJ’s Initial Decision has become the final decision of the Commissioner by operation of law.

DATES: This final decision is effective November 16, 2017.

ADDRESSES: For access to the docket, 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 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT:

Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240-402-5931.

SUPPLEMENTARY INFORMATION:

I. Background

In 1962, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) was amended by the Drug Amendments Act of 1962, and these amendments provided that new drugs could no longer be approved unless both safety and efficacy had been established for them. As amended, the FD&C Act also required FDA to evaluate drugs approved as safe between 1938 and 1962 to determine whether such drugs were effective and to withdraw approval for any new drug application (NDA) where there was not substantial evidence of the drug’s effectiveness. The person contesting the withdrawal of the approval had the burden of coming forward with evidence of effectiveness for the drug. FDA’s review of these pre-1962 drugs is known as the Drug Efficacy Study Implementation (DESI) program.

In a document published in the **Federal Register** of April 20, 1972 (37 FR 7827), after evaluating reports received from the National Academy of Sciences/National Research Council, Drug Efficacy Study Group, and other available evidence, FDA classified MFC as “possibly effective” for moderate to moderately severe pain. This document also stated that no NDA had been approved or deemed approved for MFC and that additional evidence needed to be submitted to FDA to establish MFC’s effectiveness. Thereafter, Wyeth, a division of American Home Products (Wyeth), submitted a supplement to its approved NDA 11-730 (Mepergan Injection) for MFC (NDA 11-730, S-003). In a document published in the **Federal Register** of September 18, 1981 (46 FR 46404), the Director of the Bureau of Drugs (now the Center for Drug Evaluation and Research) proposed to refuse approval of the sNDA and offered Wyeth the opportunity for a hearing.

Wyeth submitted its request for a hearing and, by a document published

in the **Federal Register** of December 31, 1984 (49 FR 50788), the Office of the Commissioner granted the hearing request. Following the submission of written testimony and documentary evidence, an ALJ, Daniel J. Davidson, conducted a hearing from January 14 to 17, 1986. He issued his Initial Decision on December 4, 1987. The ALJ found that: (1) The effectiveness of MFC had not been proven by substantial evidence of adequate and well-controlled clinical trials, (2) the requirements of the combination drug policy had not been met, and (3) MFC is a new drug under 21 U.S.C. 321(p). Wyeth timely appealed the ALJ’s Initial Decision by filing exceptions with the Commissioner under 21 CFR 12.125.

On August 23, 2017, FDA sent a letter to West-Ward Pharmaceuticals Corporation (West-Ward), successor to Wyeth, to determine whether West-Ward remained interested in pursuing its appeal of the ALJ’s Initial Decision. FDA informed the company that if it did not respond and affirm its desire to pursue its appeal by September 21, 2017, the Office of the Commissioner would conclude that West-Ward no longer wishes to pursue the appeal of the ALJ’s Initial Decision and will proceed as if the appeal has been withdrawn. The Office of the Commissioner did not receive a response from West-Ward by the given date; therefore, the Commissioner now deems the exceptions withdrawn.

II. Conclusion and Order

Given that the exceptions have been deemed withdrawn, this proceeding is now in the same procedural posture as if no exceptions had ever been filed. When parties do not file exceptions to the ALJ’s Initial Decision, and the Commissioner does not file a notice of review, the ALJ’s Initial Decision becomes the final decision of the Commissioner (see 21 CFR 12.120(e)). FDA will publish a notice in the **Federal Register** when an initial decision becomes the final decision of the Commissioner without appeal to or review by the Commissioner (see 21 CFR 12.120(f)).

Therefore, the ALJ’s Initial Decision is the final decision of the Commissioner effective November 16, 2017. Pursuant to the findings in the ALJ’s Initial Decision, under section 505(d) of the FD&C Act (21 U.S.C. 355(d)) and under the authority delegated by the Secretary of Health and Human Services, the Commissioner finds that there is a lack of substantial evidence that MFC will have the effect it purports or is represented to have under the conditions of use prescribed,