statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Deciding When to Submit a 510(k) for a Change to an Existing Device'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500054 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR part 820 are approved under OMB control number 0910–0073; the collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; and the collections of information in 21 CFR parts 801 and 809 are approved under OMB control number 0910–0485.

V. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. ''The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles,'' dated October 4, 2002, available at: *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085999.pdf.*

2. ''Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA,'' dated November 2, 2000, available at: *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073680.pdf.*

Dated: October 20, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–23197 Filed 10–24–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0655]

Animal Generic Drug User Fee Act; Recommendations; Request for Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of the Animal Generic Drug User Fee Act (AGDUFA) reauthorization draft recommendations and extending the comment period to allow interested persons 30 days to submit comments on these draft recommendations.

DATES: FDA is extending the comment period on the AGDUFA reauthorization and draft recommendations. Submit either electronic or written comments on the draft recommendations by November 24, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 24, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 24, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2011–N–0655 for ''Animal Generic Drug User Fee Act; Recommendations; Request for Comments; Extension of Comment Period'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Cassie Ravo, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6866, *cassie.ravo@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the proposed recommendations for the reauthorization of AGDUFA, which authorizes FDA to collect user fees and use them for the process of reviewing generic new animal drug applications and associated submissions. The authority for AGDUFA expires September 30, 2018. Without new legislation, FDA will no longer have the authority to collect user fees to fund the generic new animal drug review process for future fiscal years. Section 742(d)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j–22(d)(4)) requires that, after holding negotiations with regulated industry and periodic consultations with stakeholders, and before transmitting the Agency's final recommendation to Congress for the reauthorized program (AGDUFA III), we do the following: (1) Present the recommendations to the relevant Congressional committees, (2) publish such recommendations in the **Federal Register**, (3) provide for a period of 30 days for the public to provide written comments on such recommendations, (4) hold a meeting at which the public may present its views on such recommendations, and (5) consider such public views and comments and revise such recommendations as necessary. In the **Federal Register** of October 5, 2017 (82 FR 46506), we announced a public meeting to be held on November 2, 2017. In that notice we stated that we intended to publish in the **Federal Register** the full text of the proposed AGDUFA III Performance Goals and Procedures Letter and a summary of proposed statutory changes, as well as post them at *https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm270232.htm,* before the public meeting and would provide for a period of 30 days for the public to provide written comments. This notice announces the availability of these draft recommendations and extends the comment period to November 24, 2017 to provide for a period of 30 days for the public to comment on these draft recommendations. After the public meeting and closing of the comment period, we will revise the draft recommendations as necessary. In addition, the Agency will present the draft recommendations to the Congressional committees.

II. Proposed AGDUFA III Recommendations

A. Enhancing the Process for Premarket Review

We are proposing the following changes to the performance commitments previously established to further enhance the process for review of generic new animal drug applications.

Beginning October 1, 2018, all applications and submissions under section 512(b) of the FD&C Act (21 U.S.C. 360b(b)) must be submitted to the Agency electronically using the eSubmitter tool.

The Agency will review and act on 90 percent of original abbreviated new animal drug applications (ANADAs) within 240 days (180-day review plus 60-day administrative review) after the submission date. An application is incomplete if it would require additional data or information to enable the Agency to complete a comprehensive review of the application and reach a decision on the issue(s) presented in the application. If the Agency determines that the deficiencies are not substantial, the Agency will review and act on 90 percent of reactivated applications within 120 days (60-day review plus 60-day administrative review) after the reactivated ANADA submission date. This shorter review time for reactivated ANADAs for which the deficiencies are determined not to be substantial is not intended to prevent the use of minor amendments during Agency review of an application. If the Agency determines that the deficiencies are substantial or new substantial information is provided, the Agency will review and act on 90 percent of reactivated applications within 240 days (180-day review plus 60-day administrative review) after the reactivated ANADA submission date.

The Agency will review and act on 90 percent of administrative ANADAs (ANADAs submitted after all scientific decisions have been made in the generic investigational new animal drug (JINAD) process, *i.e.,* prior to the submission of the ANADA) within 60 days after the submission date. Paragraph IV certification applications (section 512(n)(1)(H)(iv) of the FD&C Act) submitted as administrative ANADAs will be excluded from the administrative ANADA cohort.

The Agency will review and act on 90 percent of Prior Approval manufacturing supplemental ANADAs within 180 days after the submission date. A Prior Approval manufacturing supplemental ANADA includes: One or more major manufacturing changes according to § 514.8(b)(2)(ii) (21 CFR 514.8(b)(2)(ii)) and in accordance with Guidance for Industry #83, ''Chemistry, Manufacturing, and Controls Changes to an Approved NADA or ANADA''; and changes submitted as ''Supplement-Changes Being Effected in 30 Days'' that require prior approval according to § 514.8(b)(3)(v)(A). If a Prior Approval supplement does not clearly identify any major manufacturing changes, the Prior Approval supplement will be designated by the Agency as a ''Supplement—Changes Being Effected'' with a 270-day review goal (see ''Supplement—Changes Being Effected Manufacturing Supplemental ANADAs and Reactivations'' below).

A submission is incomplete if it requires additional data or information to enable the Agency to complete a comprehensive review of the submission and reach a decision on the issue(s) presented in the submission. If the Agency determines that the deficiencies are not substantial for manufacturing supplements requiring prior approval, the Agency will allow the manufacturing supplements to be resubmitted as ''Supplement-Changes Being Effected in 30 Days'' as described

in § 514.8(b)(3) and the drug made with the change can be distributed 30 days after the resubmission according to § 514.8(b)(3)(iv). The Agency will review and act on 90 percent of these reactivated manufacturing supplements within 270 days after the resubmission date of a complete submission. If the Agency determines that the deficiencies remain substantial or new substantial information is provided, prior approval is required according to § 514.8(b)(3)(v)(A). The Agency will review and act on 90 percent of these reactivated manufacturing supplements within 180 days after the resubmission date of a complete submission.

The Agency will review and act on 90 percent of ''Supplement-Changes Being Effected'' manufacturing supplemental ANADAs and reactivations submitted according to § 514.8(b)(3)(vi) and in accordance with Guidance for Industry #83, ''Chemistry, Manufacturing, and Controls Changes to an Approved NADA or ANADA,'' including manufacturing changes not requiring prior approval according to § 514.8(b)(3)(iv), within 270 days after the submission date.

The Agency will review and act on 90 percent of JINAD study submissions within 180 days after the submission date.

A submission is incomplete if it would require additional data or information to enable the Agency to complete a comprehensive review of the study submission and reach a decision on the issue(s) presented in the submission. If the Agency determines that the deficiencies are not substantial, the Agency will review and act on 90 percent of resubmitted JINAD study submissions within 60 days after the receipt date of a complete study submission. This shorter review time for resubmitted JINAD study submissions is not intended to prevent the use of minor amendments during Agency review of a study submission. If the Agency determines that the deficiencies are substantial or new substantial information is provided, the Agency will review and act on 90 percent of resubmitted JINAD study submissions within 180 days after the receipt date of a complete study submission.

The Agency will review and act on 90 percent of JINAD submissions consisting of protocols without substantial data, that the Agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an ANADA or supplemental ANADA, within 75 days after the submission date.

The Agency will allow comparability protocols as described in § 514.8(b)(2)(v) to be submitted as protocols without substantial data in a JINAD file. The Agency will review and act on 90 percent of JINAD submissions consisting of protocols without substantial data within 75 days after the submission date of the protocol. For potentially more complex comparability protocols, for example sterile process validation protocols, the sponsor should discuss and have Agency concurrence regarding the appropriate filing strategy.

The Agency will continue to allow two-phased Chemistry, Manufacturing, and Controls technical section submissions under the JINAD process.

The Agency and regulated industry are committed to improving the review and business processes that will facilitate the timely scheduling and conducting of pre-approval inspections (PAIs). To improve the timeliness and predictability of foreign PAIs, sponsors may voluntarily submit: (1) At the beginning of the calendar year, a list of foreign manufacturing facilities that are specified in an abbreviated application, supplemental abbreviated application, or generic investigational file and may be subject to foreign PAIs for the following fiscal year; and (2) a notification 30 days prior to submitting an abbreviated application, a supplemental abbreviated application, or generic investigational file that informs the Agency that the application includes a foreign manufacturing facility. Should any changes to the annual list occur after its submission to the Agency, the sponsor may provide the updated information to the Agency.

The Agency will keep a record of the number of foreign PAIs conducted for abbreviated applications, along with the average time for completing the PAIs, and include this information in its annual performance report. The time for completing the PAI is understood to mean the time from the inspection scheduling request through notification to the Center for Veterinary Medicine (CVM) of inspectional findings.

The Agency and regulated industry agree that the use of both formal meetings (*e.g.,* pre-submission conferences, workshops) and informal communication by both parties is critical to ensure high submission quality such that the above performance goals can be achieved.

B. Inflation Adjuster and Workload Adjuster

The Agency and regulated industry agree to change the current fixed 4 percent inflation adjuster to a variable inflation adjuster calculated using payroll cost and benefits and the Consumer Price Index less food and energy.

The workload adjustment will continue to be calculated per CVM Program Policy and Procedures Manual 1243.3022, except that, for purposes of calculating the workload adjustment, it is agreed to reset the base years to fiscal year (FY) 2014 through FY 2018. There will be no workload adjustment for FY 2019. Workload adjustments are one-time adjustments and are calculated annually.

C. Offset Provision and Excess Collections

The proposal adds financial flexibility by eliminating the final year offset of the over collections provision and making any excess collections available to enhance the review process in real time. In addition, the proposal provides authority for the Secretary of Health and Human Services when setting fees to reduce a calculated workload adjustment up to the amount of excess collections in the second preceding fiscal year. The first fiscal year this provision could be applied while setting fees is fiscal year 2021.

D. Impact of AGDUFA III Changes on User Fee Revenue

The FY 2019 baseline for AGDUFA III is $18,336,340. For each year from FY 2020 through FY 2023, the annual statutory revenue amounts established in section 741(b) of the FD&C Act (21 U.S.C. 379j–21(b)) will be further adjusted according to the new statutory provision for the inflation adjuster and may be further adjusted by the workload adjuster, if applicable.

The planned total 5-year revenue for AGDUFA I was $27,100,000. The planned total 5-year revenue for AGDUFA II was $38,100,000, which also included one-time information technology funding in the amount of $850,000 for FY 2014. It is estimated that the planned total 5-year revenue for AGDUFA III will be $95,000,000.

The fee revenue distribution in AGDUFA III will remain the same as AGDUFA II: 25 percent in application fees; 37.5 percent in product fees; and 37.5 percent in sponsor fees.

Dated: October 20, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–23173 Filed 10–24–17; 8:45 am]

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