information submitted will be used by the agency to ensure compliance with the statute; to monitor, evaluate, and measure grantee achievements in addressing the investigation and prosecution of child abuse and neglect; and to report to Congress.

Respondents: State governments.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Application and Annual Report	52	1	60	3,120

Estimated Total Annual Burden Hours: 3,120.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 5106c Sec. 107 (b)4; and 42 U.S.C. 5106 Sec. 107 (B)5.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–25223 Filed 11–18–22; 8:45 am]

BILLING CODE 4184–25–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0656]

Animal Drug User Fee Act; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''Animal Drug User Fee Act.'' The purpose of the public meeting is to discuss the proposed recommendations for the reauthorization of the Animal Drug User Fee Act (ADUFA V) for fiscal years 2024 through 2028.

DATES: The public meeting will be held virtually on December 7, 2022, from 1 p.m. to 3 p.m. Eastern Time. Either electronic or written comments on this public meeting must be submitted by December 19, 2022. See the **SUPPLEMENTARY INFORMATION** section for registration date and further information.

ADDRESSES: The public meeting will be hosted via a live virtual webcast.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 19, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–0656 for ''Animal Drug User Fee Act; Public Meeting; Request for Comments.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

Transcripts of the meeting will be available on FDA's website at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings* approximately 30 days after the meeting.

FOR FURTHER INFORMATION CONTACT: Lisa Kable, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6888, *lisa.kable@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a virtual public meeting to discuss proposed recommendations for the reauthorization of ADUFA, which authorizes FDA to collect user fees and use them for the process of reviewing new animal drug applications and associated submissions. The authority for ADUFA expires September 30, 2023. Without new legislation, FDA will no longer have the authority to collect user fees to fund the new animal drug review process for future fiscal years. Section 740A(d)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–13(d)(4)) requires that, after holding negotiations with regulated industry and periodic consultations with stakeholder, and before transmitting the Agency's final recommendation to Congress for the reauthorized program (ADUFA V), we do the following: (1) present the recommendation 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. This notice, the 30-day comment period, and the public meeting will satisfy certain of these requirements. After the public meeting, we will revise the draft recommendations as necessary. In addition, the Agency will present the draft recommendations to the Congressional committees.

FDA considers the timely review of the safety and effectiveness of new animal drug applications (NADAs) to be central to the Agency's mission to protect and promote human and animal health. Prior to 2004, the timeliness and predictability of the new animal drug review program was a concern. The Animal Drug User Fee Act of 2003 (Pub. L. 108–130; hereinafter referred to as ''ADUFA I'') authorized FDA to collect user fees dedicated to the timely review of new animal drug applications in accordance with certain performance goals and to expand and modernize the new animal drug review program from fiscal year (FY) 2004 to 2008. The Agency agreed, under ADUFA I, to meet a comprehensive set of performance goals established to show significant improvement in the timeliness and predictability of the new animal drug review process. The implementation of ADUFA I provided a significant funding increase that enabled FDA to increase the number of staff dedicated to the new animal drug application review process by 30 percent in ADUFA I.

With the reauthorization of ADUFA for an additional 5 years under ADUFA II (FY 2009 to FY 2013), FDA agreed to further enhance and improve the review process. ADUFA II performance goals were established based on ADUFA I FY 2008 review timeframes. In addition, FDA provided program enhancements to reduce review cycles and improve communications during reviews. The ADUFA programs have enabled FDA to meet performance timeframes for application review for new animal drugs without compromising the quality of the Agency's review.

The ADUFA III reauthorization (FY 2014 to FY 2018) maintained the FY 2013 review timeframes for key submissions in addition to enhancements to the program. Enhancements included: replacing the End Review Amendment with a short, second-round review; reducing time for microbial food safety hazard characterization submissions to 100 days; and changes to the financial structure. There were also chemistry, manufacturing, and controls (CMC) enhancements, including developing guidance for a two-phased CMC technical section submission and review process under the investigational new animal drug file.

Most recently, ADUFA was reauthorized for an additional 5 years under ADUFA IV (FY 2019 to FY 2023). The ADUFA IV authorization enhancements included adding new performance goals for presubmission conferences and tissue residue method trial demonstrations, requiring 100 percent electronic submissions, and requiring an ''approved by FDA'' statement along with a NADA number on approved animal drugs by September 30, 2023. Additionally, a new provision was added that any excess collections would be used to offset workload adjuster or shortfall fee increases, if invoked.

FDA has published a number of reports that provide useful background on ADUFA I, II, III, and IV. ADUFA-related **Federal Register** notices, guidances, legislation, performance reports, and financial reports can be found at: *https://www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa.*

II. Topics for Discussion at the Public Meeting

In preparing the proposed recommendation to Congress for ADUFA reauthorization, we conducted discussions with the regulated industry, and consulted with stakeholders as required by the law. We began the ADUFA reauthorization process with a public meeting held on May 20, 2021 (86 FR 18989, April 12, 2021). Following the May 2021 public meeting, FDA conducted negotiations with regulated industry and continued regular consultations with public stakeholders from October 2021 through August 2022. As directed by Congress, FDA posted minutes of these discussions on its website at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings.*

The proposed enhancements in ADUFA V will address priorities identified by stakeholders, regulated industry, and FDA. The full description of these proposed recommendations can be found in the proposed ADUFA V Performance Goals and Procedures Letter. FDA intends to post the full text of the proposed ADUFA V Performance Goals and Procedures Letter at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings,* no later than 1 week prior to the public meeting. FDA will post the agenda approximately 5 days before the meeting at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings.*

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register online at *https://fda.zoomgov.com/webinar/register/WN_DBPaDGi5QXaaCoxkJkx7g* no later than December 5, 2022. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Also, please self-identify as a member of one of the following stakeholder categories: scientific or academic experts, veterinary professionals, patients and consumer advocacy groups, or the regulated industry, and whether you are requesting a scheduled presentation.

Early registration is recommended. Registrants will receive confirmation when their registration has been received and will be provided the webcast link.

If you need special accommodations due to a disability, please contact Lisa Kable (see **FOR FURTHER INFORMATION CONTACT**) no later than December 1, 2022.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during the public comment session and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate.

We will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and we will notify participants by December 5, 2022. All requests to make oral presentations must be received by December 1, 2022, 11:59 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to Lisa Kable (see **FOR FURTHER INFORMATION CONTACT**) no later than December 5, 2022. No commercial or promotional material will be permitted to be presented at the public meeting.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings.*

Dated: November 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–25274 Filed 11–18–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2826]

Allergan Sales, LLC, et al.; Withdrawal of Approval of 10 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 10 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of December 21, 2022.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040099	Norco (hydrocodone bitartrate and acetaminophen) Tablets, 5 milligrams (mg)/325 mg.	Allergan Sales, LLC, U.S. Agent for Allergan Pharmaceuticals International Limited, 5 Giralda Farms, Madison, NJ 07940.
ANDA 040148	Norco (hydrocodone bitartrate and acetaminophen) Tablets, 2.5 mg/325 mg, 5 mg/325 mg, 7.5 mg/325 mg, 10 mg/325 mg, and 10 mg/500 mg.	Do.
ANDA 076434	Chlorhexidine Gluconate Solution, 0.12%	Sunstar Americas, Inc., 301 East Central Rd., Schaumburg, IL 60195.
ANDA 079076	Ranitidine Hydrochloride (HCl) Injection, Equivalent to (EQ) 25 mg base/milliliters (mL).	Mylan Pharmaceuticals Inc., a Viatris Company, U.S. Agent for Mylan Laboratories Limited, 3711 Collins Ferry Rd., Morgantown, WV 26505.
ANDA 090054	Ranitidine HCl Syrup, EQ 15 mg base/mL	Tolmar Inc., 701 Centre Ave., Fort Collins, CO 80526.
ANDA 201804	Letrozole Tablets, 2.5 mg	Indicus Pharma, LLC, 2530 Meridian Parkway, Durham, NC 27713.
ANDA 201832	Nimodipine Capsules, 30 mg	Sofgen Pharmaceuticals, LLC, 21500 Biscayne Blvd., Suite 600, Aventura, FL 33180.
ANDA 203419	Donepezil HCl Tablets, 23 mg	Indicus Pharma, LLC.
ANDA 203519	Morphine Sulfate Solution, 20 mg/5 mL	Tris Pharma, Inc., 2033 Route 130, Suite D, Monmouth Junction, NJ 08852.
ANDA 206151	Abacavir Sulfate and Lamivudine Tablets, EQ 600 mg base; 300 mg.	Aurobindo Pharma USA, Inc., U.S. Agent for Aurobindo Pharma Limited, 279 Princeton-Hightstown Rd., East Windsor, NJ 08520.