

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. FDA-2017-P-0840]

Determination That OVRETTE (Norgestrel) Tablet, 0.075 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness
AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that OVRETTE (norgestrel) tablet, 0.075 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for norgestrel tablet, 0.075 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Daniel Gottlieb, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6217, Silver Spring, MD 20993-0002, 301-796-6650.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to FDA’s approval of an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

OVRETTE (norgestrel) tablet, 0.075 mg, is the subject of NDA 017031, held by HRA Pharma and initially approved on October 23, 1973. OVRETTE is indicated for the prevention of pregnancy in women.

OVRETTE (norgestrel) tablet, 0.075 mg, was discontinued from U.S. distribution on June 7, 2005, and is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

The Weinberg Group submitted a citizen petition dated February 8, 2017 (Docket No. FDA-2017-P-0840), under 21 CFR 10.30, requesting that the Agency determine whether OVRETTE (norgestrel) tablet, 0.075 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that OVRETTE (norgestrel) tablet, 0.075 mg, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that OVRETTE (norgestrel) tablet, 0.075 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of OVRETTE (norgestrel) tablet, 0.075 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list OVRETTE (norgestrel) tablet, 0.075 mg, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to this drug product may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that

labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: October 17, 2017.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2017-23125 Filed 10-24-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. FDA-2011-N-0656]

Animal 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 Drug User Fee Act (ADUFA) 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 ADUFA 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 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-0656 for "Animal 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 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, 2018. 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 (the FD&C Act) (21 U.S.C. 379j-13(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 (ADUFA IV), 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. In the **Federal Register** of October 5, 2017 (82 FR 46503), 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 ADUFA IV Performance Goals and Procedures Letter and a summary of proposed statutory changes, as well as post them at <https://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042891.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 ADUFA IV 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 new animal drug applications (NADAs).

Beginning October 1, 2018, all applications and submissions under section 512(b) and 571 of the FD&C Act (21 U.S.C. 360b(b) and 21 U.S.C. 360ccc, respectively) must be submitted to the Agency electronically using the eSubmitter tool.

The Agency will review and act on 90 percent of "Supplement-Changes Being Effected" manufacturing supplemental NADAs and reactivations submitted according to § 514.8(b)(3)(vi) (21 CFR 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 180 days after the submission date. All other application and submission performance goals will remain the same as ADUFA III.

The Agency commits to working on implementation of the United States-European Union Good Manufacturing

Practice Inspection Mutual Recognition Agreement. All other commitments related to pre-approval inspections will remain the same as ADUFA III.

The Agency will review and act on 90 percent of qualifying Animal Drug Availability Act (ADAA) combination medicated feed applications within 60 days after the submission date when all of the following conditions are met:

- Basic regulatory requirements for an ADAA combination medicated feed application has been met as outlined in 21 CFR 514.4(c)(2)(ii).
- A presubmission conference has been conducted and either:
 - No data (no tissue residue non-interference study is required) are needed and this agreement is documented in the memorandum of conference for the presubmission conference; or
 - A justification for not conducting a tissue residue non-interference study has been submitted, reviewed, and found acceptable under an investigational new animal drug (INAD), prior to the submission of the ADAA combination medicated feed application; or
 - A tissue residue non-interference study has been submitted, reviewed, and found acceptable under an INAD, prior to the submission of the ADAA combination medicated feed application.
- No effectiveness or target animal safety data are required.
- No manufacturing data requirements—sponsor can address in meeting assay non-interference, but data submission is not required.
- All other information is referenced to previous drug experience reports.
- Sponsor makes submission and it includes: Representative (Blue Bird) labeling, Veterinary Feed Directive (if applicable).
- Includes a request for categorical exclusion from the need to prepare an environmental assessment (EA); *i.e.*, no EA required.
- Reference to presubmission conference.
- Right of reference (if applicable) to NADA(s) not owned by the filing sponsor of the ADAA combination medicated feed application has been received by the Agency.

The Agency will review and act on 90 percent of ADAA combination medicated feed applications within 100 days for those applications accepted for the 60-day timeframe and there is a need for minor amendments.

If any of the above conditions cannot be met, the ADAA combination medicated feed application performance metric will be placed in the original

NADA application cohort with a 180-day review timeframe.

The Agency will review and act on 90 percent of resubmissions of previously completed Environmental Impact technical sections within 60 days after the submission date where:

- A categorical exclusion was issued;
- All other technical sections have been submitted; and
- Information contained in the other technical sections reveals a change in the conditions of use of the previously issued categorical exclusion.

The Agency will conduct 90 percent of qualifying presubmission conferences within a 60-day timeframe when all of the following conditions are met:

- All background materials, including presentations, have been submitted, and
- A complete agenda has been agreed upon by the Agency and the sponsor.

A sponsor and the Agency can mutually agree to exclude a particular presubmission conference from this performance goal. If a sponsor accepts a date beyond the 60-day timeframe for their scheduling purposes or is unable to meet with the Agency on Agency available dates, the submission will be excluded from the presubmission conference cohort.

The Agency will commence 90 percent of tissue residue method demonstrations within 120 days of completion of the 3-hour meeting process or within 200 days from the receipt of a submission that supports a single laboratory validation tissue residue method demonstration.

B. Inflation Adjuster and Workload Adjuster

The inflation adjuster will remain the same as for ADUFA III.

The workload adjustment will continue to be calculated per Center for Veterinary Medicine Program Policy and Procedures Manual 1243.3022, except that, for purposes of calculating the workload adjustment, it has been 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 over collections provision and making any excess collections available to enhance the review process in real time. The proposal provides authority for the Secretary of Health and Human Services (the Secretary) 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 FY 2021. Likewise, the proposal also provides authority to the Secretary to reduce an increase in fees to recover a shortfall in collections in a preceding year (after 2018) by any remaining prior year excess collections not already applied for purposes of reducing fee increases.

D. Impact of ADUFA IV Enhancements on User Fee Revenue

The FY 2019 baseline for ADUFA IV is \$30,331,240, which includes a \$400,000 one-time cost for information technology enhancement. 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 by the inflation adjuster, the workload adjuster, if applicable, and will include \$900,000 per year for tissue method trials.

The total 5-year revenue planned for ADUFA I was \$47,000,000. The total 5-year revenue planned for ADUFA II was \$98,000,000. The total 5-year revenue planned for ADUFA III was \$114,000,000. It is estimated that the total 5-year revenue for ADUFA IV will be \$150,000,000.

The fee revenue distribution in ADUFA IV will remain the same as ADUFA III: 20 percent from application fees; 27 percent from product fees; 26 percent from establishment fees; and 27 percent from sponsor fees.

Dated: October 20, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–23172 Filed 10–24–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2021]

Deciding When To Submit a 510(k) for a Software Change to an Existing Device; Guidance for Industry and Food and Drug Administration Staff; 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 the guidance entitled “Deciding When to Submit a 510(k) for a Software Change