Description of Respondents: Respondents to this collection of information are new animal drug applicants and abbreviated new animal drug applicants. In addition, requests for waivers or reductions of user fees may be submitted by a person responsible for paying or potentially responsible for paying any of the animal drug user fees assessed, including application fees, product fees, establishment fees, or sponsor fees.

In the **Federal Register** of January 23, 2020 (85 FR 3929), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C act section; activity	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
User Fee Cover Sheets, by Type						
740(a)(1); Animal Drug User Fee Cover Sheet	FDA 3546	21	1	21	1	21
741; Animal Generic Drug User Fee Cover Sheet	FDA 3728	20	2	40	0.08 (5 minutes)	3
Waivers and Other Requests, by Type						
740(d)(1)(A); significant barrier to innovation	N/A	55	1	55	2	110
740(d)(1)(B); fees exceed cost	N/A	8	3.75	30	0.5 (30 minutes)	15
740(d)(1)(C); free-choice feeds	N/A	5	1	5	2	10
740(d)(1)(D); minor use or minor species	N/A	69	1	69	2	138
740(d)(1)(E); small business	N/A	1	1	1	2	2
Request for reconsideration of a decision	N/A	1	1	1	2	2
Request for review (user fee appeal officer)	N/A	1	1	1	2	2
Total						303

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

For the purpose of this consolidation, we rely on our previous estimates of the number of user fee cover sheet and waiver and other request submissions. We estimate 21 respondents will each submit 1 Animal Drug User Fee cover sheet (Form FDA 3546) for a total of 21 responses. We estimate 20 respondents will each submit 2 Animal Generic Drug User Fee cover sheets (Form FDA 3728) for a total of 40 responses. Our estimate of the number of waiver and other request submissions is detailed in table 1. These estimates are consistent with our previous estimates except for the row labeled, Request for review (user fee appeal officer), for which we have increased the estimated number of respondents from zero to one and the average burden per response from 0 to 2 hours to correct the error in our previous submission. We base our estimates of the average burden per response on our experience with the submission of similar cover sheets and waiver and other requests.

The information collection reflects an increase in burden by an additional 26 hours and 62 responses due to the consolidation of the information collections covered by OMB control numbers 0910–0539, ''Animal Drug User Fee Cover Sheet,'' and 0910–0632, ''Animal Generic Drug User Fee Cover Sheet'' and the correction of the error in our previous submission.

Dated: June 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14263 Filed 7–1–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–P–1072]

Determination That ZOVIRAX (Acyclovir) Oral Capsules, 200 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 ZOVIRAX (acyclovir) oral capsules, 200 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will also allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Jessica Tierney, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–9120, *Jessica.Tierney@fda.hhs.gov.*

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 approving 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.

ZOVIRAX (acyclovir) oral capsules, 200 mg, is the subject of NDA 018828, held by Mylan Pharmaceuticals Inc., and initially approved on January 25, 1985. ZOVIRAX is indicated for the acute treatment of herpes zoster (shingles), the treatment of initial episodes and the management of recurrent episodes of genital herpes, and the treatment of chickenpox (varicella).

ZOVIRAX (acyclovir) oral capsules, 200 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Yiling Pharmaceuticals Ltd. submitted a citizen petition dated March 10, 2020 (Docket No. FDA–2020–P–1072), under 21 CFR 10.30, requesting that the Agency determine whether ZOVIRAX (acyclovir) oral capsules, 200 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 ZOVIRAX (acyclovir) oral capsules, 200 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ZOVIRAX (acyclovir) oral capsules, 200 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ZOVIRAX (acyclovir) oral capsules, 200 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ZOVIRAX (acyclovir) oral capsules, 200 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug may also 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: June 23, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14269 Filed 7–1–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Promoting the Rule of Law Through Improved Agency Guidance Documents

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: On October 9, 2019, the President issued Executive Order (E.O.) 13891: *Promoting the Rule of Law Through Improved Agency Guidance Documents.* This E.O. requires all Federal agencies to establish an on-line guidance portal and to rescind any guidance documents that are no longer active or valid.

FOR FURTHER INFORMATION CONTACT: Samuel Shipley, Executive Secretariat, at *Guidance@hhs.gov* or (202) 690–5627.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) granted the Department of Health and Human Services (HHS) an extension on February 27, 2020, allowing HHS until August 31, 2020, to establish its guidance portal. This extension request can be found at: *https://www.hhs.gov/sites/default/files/eo-13891-extension-request-2-27-20r.pdf.*

Consistent with the E.O. and subsequent extension, this document advises the public that HHS has comprehensively reviewed its guidance documents, determined which have continued effect, and is making them available on *https://www.hhs.gov/guidance.*

This guidance portal includes all active guidance documents from across the HHS's 27 Operating and Staff Divisions. Please note: While many of the Centers for Medicare & Medicaid Services' (CMS) active guidance documents are included here, this does not reflect CMS's full inventory. OMB granted CMS an extension until July 31, 2020, to fully populate the database.

Dated: June 29, 2020.

Wilma M. Robinson,

Deputy Executive Secretary, Department of Health and Human Services.

[FR Doc. 2020–14433 Filed 7–1–20; 8:45 am]

BILLING CODE 4150–03–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2020–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities. The flood hazard determinations modified by each LOMR will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: Each LOMR was finalized as in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *https://msc.fema.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs