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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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under 21 CFR 10.30, requesting that the Agency determine whether ZOVIRAX (acyclovir) oral capsules, 200 mg, was withdrawn from sale for reasons of safety or effectiveness.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we have at this time, FDA has determined under § 314.161 that ZOVIRAX (acyclovir) oral capsules, 200 mg, was not withdrawn for reasons of safety or effectiveness.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petitioner has identified no data or other information suggesting that ZOVIRAX (acyclovir) oral capsules, 200 mg, was withdrawn for reasons of safety or effectiveness.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 We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.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