

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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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under 21 CFR 10.30, requesting that the Agency determine whether ZOVIRAX (acyclovir) oral capsules, 200 mg, was withdrawn from sale for reasons of safety or effectiveness.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we have at this time, FDA has determined under § 314.161 that ZOVIRAX (acyclovir) oral capsules, 200 mg, was not withdrawn for reasons of safety or effectiveness.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petitioner has identified no data or other information suggesting that ZOVIRAX (acyclovir) oral capsules, 200 mg, was withdrawn for reasons of safety or effectiveness.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 We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.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

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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.

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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

for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the

floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the

floodplain management requirements of the NFIP and are used to calculate the appropriate flood insurance premium rates for new buildings, and for the contents in those buildings. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at <https://msc.fema.gov>.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Alaska: Juneau (FEMA Docket No.: B-2021).	City and Borough of Juneau (19-10-1198P).	The Honorable Beth Weldon, Mayor, City and Borough of Juneau, 155 South Seward Street, Juneau, AK 99801.	Community Development Department, 155 South Seward Street, Juneau, AK 99801.	May 26, 2020	020009
Colorado:					
Arapahoe (FEMA Docket No.: B-2008).	City of Aurora (19-08-0618P).	The Honorable Bob LeGare, Mayor, City of Aurora, 15151 East Alameda Parkway, Aurora, CO 80012.	Engineering Department, 15151 East Alameda Parkway, Aurora, CO 80012.	May 15, 2020	080002
Arapahoe (FEMA Docket No.: B-2008).	City of Centennial (19-08-0618P).	The Honorable Stephanie Piko, Mayor, City of Centennial, 13133 East Arapahoe Road, Centennial, CO 80112.	Southeast Metro Stormwater Authority, 76 Inverness Drive East, Suite A, Englewood, CO 80112.	May 15, 2020	080315
Arapahoe (FEMA Docket No.: B-2008).	Unincorporated areas of Arapahoe County (19-08-0618P).	The Honorable Jeff Baker, Chairman, Arapahoe County Board of Commissioners, 5334 South Prince Street, Littleton, CO 80120.	Arapahoe County Public Works and Development Department, 6924 South Lima Street, Centennial, CO 80112.	May 15, 2020	080011
Broomfield (FEMA Docket No.: B-2016).	City and County of Broomfield (19-08-0385P).	The Honorable Patrick Quinn, Mayor, City and County of Broomfield, 1 DesCombes Drive, Broomfield, CO 80020.	Engineering Department, 1 DesCombes Drive, Broomfield, CO 80020.	May 29, 2020	085073
Broomfield (FEMA Docket No.: B-2016).	City and County of Broomfield (19-08-0494P).	The Honorable Patrick Quinn, Mayor, City and County of Broomfield, 1 DesCombes Drive, Broomfield, CO 80020.	Engineering Department, 1 DesCombes Drive, Broomfield, CO 80020.	May 22, 2020	085073
Jefferson (FEMA Docket No.: B-2016).	City of Westminster (19-08-0494P).	The Honorable Herb Atchison, Mayor, City of Westminster, 4800 West 92nd Avenue, Westminster, CO 80031.	City Hall, 4800 West 92nd Avenue, Westminster, CO 80031.	May 22, 2020	080008
Douglas (FEMA Docket No.: B-2008).	Unincorporated areas of Douglas County (19-08-0888P).	The Honorable Roger A. Partridge, Chairman, Douglas County Board of Commissioners, 100 3rd Street, Castle Rock, CO 80104.	Public Works Engineering Division, 100 3rd Street, Castle Rock, CO 80104.	May 15, 2020	080049
Connecticut:					
Fairfield (FEMA Docket No.: B-2021).	Town of Greenwich (19-01-1421P).	The Honorable Peter J. Tesei, First Selectman, Town of Greenwich Board of Selectmen, 101 Field Point Road, Greenwich, CT 06830.	Planning and Zoning Department, 101 Field Point Road, Greenwich, CT 06830.	May 26, 2020	090008
New Haven (FEMA Docket No.: B-2016).	Town of Cheshire (20-01-0003P).	The Honorable Rob Oris, Jr., Chairman, Town of Cheshire Council, 84 South Main Street, Cheshire, CT 06410.	Town Hall, 84 South Main Street, Cheshire, CT 06410.	May 15, 2020	090074
Florida:					
Collier (FEMA Docket No.: B-2021).	City of Marco Island (20-04-0464P).	Mr. Michael T. McNees, City of Marco Island Manager, 50 Bald Eagle Drive, Marco Island, FL 34145.	Building Services Department, 50 Bald Eagle Drive, Marco Island, FL 34145.	May 29, 2020	120426
Hillsborough (FEMA Docket No.: B-2008).	City of Tampa (19-04-6204P).	The Honorable Jane Castor, Mayor, City of Tampa, 306 East Jackson Street, Tampa, FL 33602.	Development Services Department, 1400 North Boulevard, Tampa, FL 33607.	May 18, 2020	120114
Monroe (FEMA Docket No.: B-2021).	Village of Islamorada (20-04-0305P).	The Honorable Mike Forster, Mayor, Village of Islamorada, 86800 Overseas Highway, Islamorada, FL 33036.	Building Department, 86800 Overseas Highway, Islamorada, FL 33036.	May 28, 2020	120424
Wakulla (FEMA Docket No.: B-2016).	Unincorporated areas of Wakulla County (19-04-3034P).	The Honorable Mike Stewart, Chairman, Wakulla County Board of Commissioners, 3093 Crawfordville Highway, Crawfordville, FL 32327.	Wakulla County Planning and Community Development Department, 3093 Crawfordville Highway, Crawfordville, FL 32327.	Jun. 5, 2020	120315

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Georgia: Cherokee (FEMA Docket No.: B-2016).	Unincorporated areas of Cherokee County (19-04-4793P).	The Honorable Harry Johnston, Chairman, Cherokee County Board of Commissioners, 1130 Bluffs Parkway, Canton, GA 30114.	Cherokee County Engineering Department, 1130 Bluffs Parkway, Canton, GA 30114.	May 15, 2020	130424
Massachusetts: Essex (FEMA Docket No.: B-2016).	Town of Nahant (19-01-1429P).	The Honorable Richard Lombard, Chairman, Town of Nahant Board of Selectmen, 334 Nahant Road, Nahant, MA 01908.	Public Works Department, 334 Nahant Road, Nahant, MA 01908.	May 12, 2020	250095
Michigan: Washtenaw (FEMA Docket No.: B-2016).	City of Ann Arbor (19-05-2230P).	The Honorable Christopher Taylor, Mayor, City of Ann Arbor, 301 East Huron Street, Ann Arbor, MI 48107.	City Hall, 301 East Huron Street, Ann Arbor, MI 48107.	May 22, 2020	260213
New Mexico: Santa Fe (FEMA Docket No.: B-2016).	City of Santa Fe (19-06-2643P).	The Honorable Alan Webber, Mayor, City of Santa Fe, 200 Lincoln Avenue, Santa Fe, NM 87504.	Building Permits Department, 200 Lincoln Avenue, Santa Fe, NM 87504.	May 20, 2020	350070
North Carolina: Martin (FEMA Docket No.: B-2016).	Town of Williamston (19-04-2709P).	The Honorable Joyce Whichard-Brown, Mayor, Town of Williamston, P.O. Box 506, Williamston, NC 27892.	Planning and Zoning Department, 102 East Main Street, Williamston, NC 27892.	May 14, 2020	370157
Oklahoma: Canadian (FEMA Docket No.: B-2016).	City of El Reno (19-06-2199P).	The Honorable Matt White, Mayor, City of El Reno, P.O. Drawer 700, El Reno, OK 73036.	City Hall, 101 North Choctaw Avenue, El Reno, OK 73036.	May 14, 2020	405377
Pennsylvania: Chester (FEMA Docket No.: B-2016).	Township of West Goshen (19-03-1653P).	Mr. Casey LaLonde, Township of West Goshen Manager, 1025 Paoli Pike, West Chester, PA 19380.	Township Hall, 1025 Paoli Pike, West Chester, PA 19380.	Jun. 8, 2020	420293
South Carolina: Georgetown (FEMA Docket No.: B-2016).	Unincorporated areas of Georgetown County (19-04-6326P).	Mr. Sel Hemingway, Georgetown County Administrator, 716 Prince Street, Georgetown, SC 29440.	Georgetown County Building Department, 129 Screven Street, Georgetown, SC 29440.	Jun. 4, 2020	450085
Texas:					
Bexar (FEMA Docket No.: B-2021).	City of San Antonio (19-06-1791P).	The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Transportation and Capitol Improvements Department, Storm Water Division, 114 West Commerce Street, 7th Floor, San Antonio, TX 78204.	May 18, 2020	480045
Bexar (FEMA Docket No.: B-2021).	Unincorporated areas of Bexar County (19-06-1791P).	The Honorable Nelson W. Wolff, Bexar County Judge, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205.	Bexar County Public Works Department, 1948 Probandt Street, San Antonio, TX 78214.	May 18, 2020	480035
Collin (FEMA Docket No.: B-2008).	City of Celina (19-06-2325P).	The Honorable Sean Terry, Mayor, City of Celina, 142 North Ohio Street, Celina, TX 75009.	City Hall, 142 North Ohio Street, Celina, TX 75009.	May 18, 2020	480133
Collin (FEMA Docket No.: B-2008).	Unincorporated areas of Collin County (19-06-2325P).	The Honorable Chris Hill, Collin County Judge, 2300 Bloomdale Road, Suite 4192, McKinney, TX 75071.	Collin County Engineering Department, 4690 Community Avenue, Suite 200, McKinney, TX 75071.	May 18, 2020	480130
McLennan (FEMA Docket No.: B-2016).	City of McGregor (19-06-1286P).	The Honorable James S. Hering, Mayor, City of McGregor, 302 South Madison Avenue, McGregor, TX 76657.	City Hall, 302 South Madison Avenue, McGregor, TX 76657.	May 19, 2020	480459
McLennan (FEMA Docket No.: B-2016).	Unincorporated areas of McLennan County (19-06-1286P).	The Honorable Scott M. Felton, McLennan County Judge, 501 Washington Avenue, Suite 214, Waco, TX 76701.	McLennan County Engineering and Mapping Department, 215 North 5th Street, Suite 130, Waco, TX 76701.	May 19, 2020	480456
Tarrant (FEMA Docket No.: B-2016).	City of Fort Worth (19-06-2910P).	The Honorable Betsy Price, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	Transportation and Public Works Department, 200 Texas Street, Fort Worth, TX 76102.	May 18, 2020	480596
Travis (FEMA Docket No.: B-2016).	City of Manor (19-06-2660P).	The Honorable Larry Wallace, Jr., Mayor, City of Manor, P.O. Box 387, Manor, TX 78653.	City Hall, 105 East Eggleston Street, Manor, TX 78653.	Jun. 1, 2020	481027
Travis (FEMA Docket No.: B-2016).	Unincorporated areas of Travis County (19-06-2660P).	The Honorable Sarah Eckhardt, Travis County Judge, P.O. Box 1748, Austin, TX 78767.	Travis County Transportation and Natural Resources Department, 700 Lavaca Street, 5th Floor, Austin, TX 78701.	Jun. 1, 2020	481026
Utah:					
Wasatch (FEMA Docket No.: B-2016).	Town of Wallsburg (19-08-0779P).	The Honorable Celeni Richins, Mayor, Town of Wallsburg, 70 West Main Street, Wallsburg, UT 84082.	Town Hall, 70 West Main Street, Wallsburg, UT 84082.	May 28, 2020	490168
Wasatch (FEMA Docket No.: B-2016).	Unincorporated areas of Wasatch County (19-08-0779P).	Mr. Mike Davis, Wasatch County Manager, 25 North Main Street, Heber City, UT 84032.	Wasatch County Community Services Department, 55 South 500 East, Heber City, UT 84032.	May 28, 2020	490164