

advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss new drug application (NDA) 204803, bupivacaine extended-release solution for instillation, submitted by DURECT Corp., for the proposed indication of post-surgical analgesia. The committee will discuss whether the Applicant adequately demonstrated the safety and efficacy of bupivacaine extended-release solution for post-surgical analgesia and the appropriateness of the proposed patient populations. The committee will also be asked to discuss the approvability of this product.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before January 2, 2020, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 20, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 23, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Moon Hee V. Choi (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-25278 Filed 11-20-19; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2019-0002; Internal Agency Docket No. FEMA-B-1973]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt

or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before February 19, 2020.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location <https://www.fema.gov/preliminaryfloodhazarddata> and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at <https://msc.fema.gov> for comparison.

You may submit comments, identified by Docket No. FEMA-B-1973, to 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.

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 Map Information eXchange (FMIX) online at https://www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, 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. These 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 built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of

experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at https://www.floodsrp.org/pdfs/srp_overview.pdf.

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location <https://>

www.fema.gov/preliminaryfloodhazarddata and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at <https://msc.fema.gov> for comparison. (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.

| Community | Community map repository address |
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| Cumberland County, Pennsylvania (All Jurisdictions) | |
| Project: 15-03-0142S Preliminary Date: May 14, 2019 | |
| Borough of Camp Hill | Borough Administration Office, 2145 Walnut Street, Camp Hill, PA 17011. |
| Borough of Carlisle | Municipal Building, 53 West South Street, Carlisle, PA 17013. |
| Borough of Lemoyne | Borough Office, 510 Herman Avenue, Lemoyne, PA 17043. |
| Borough of Mechanicsburg | Borough Office, 36 West Allen Street, Mechanicsburg, PA 17055. |
| Borough of Mount Holly Springs | Municipal Building, 200 Harman Street, Mount Holly Springs, PA 17065. |
| Borough of Newburg | Borough Office, 105 West Main Street, Newburg, PA 17240. |
| Borough of New Cumberland | Borough Office, 1120 Market Street, New Cumberland, PA 17070. |
| Borough of Newville | Borough Office, 4 West Street, Newville, PA 17241. |
| Borough of Shippensburg | Borough Office, 111 North Fayette Street, Shippensburg, PA 17257. |
| Borough of Shiremanstown | Borough Office, 1 Park Lane, Shiremanstown, PA 17011. |
| Borough of Wormleysburg | Borough Hall, 20 Market Street, Wormleysburg, PA 17043. |
| Township of Cooke | Cooke Township Office, 1700 Centerville Road, Newville, PA 17241. |
| Township of Dickinson | Dickinson Township Building, 219 Mountain View Road, Mount Holly Springs, PA 17065. |
| Township of East Pennsboro | East Pennsboro Township Community and Municipal Center, 98 South Enola Drive, Enola, PA 17025. |
| Township of Hampden | Hampden Township Municipal Building, 230 South Sporting Hill Road, Mechanicsburg, PA 17050. |
| Township of Hopewell | Hopewell Township Administration Building, 415 Three Square Hollow Road, Newburg, PA 17240. |
| Township of Lower Allen | Lower Allen Township Municipal Services Center, 2233 Gettysburg Road, Camp Hill, PA 17011. |
| Township of Lower Frankford | Lower Frankford Township Municipal Building, 1205 Easy Road, Carlisle, PA 17015. |
| Township of Lower Mifflin | Lower Mifflin Township Office, 529 Shed Road, Newville, PA 17241. |
| Township of Middlesex | Middlesex Township Building, 350 North Middlesex Road, Carlisle, PA 17013. |
| Township of Monroe | Monroe Township Municipal Complex, 1220 Boiling Springs Road, Mechanicsburg, PA 17055. |
| Township of North Middleton | North Middleton Township Municipal Building, 2051 Spring Road, Carlisle, PA 17013. |
| Township of North Newton | North Newton Township Administrative Office, 528 Oakville Road, Shippensburg, PA 17257. |
| Township of Penn | Penn Township Municipal Building, 1301 Centerville Road, Newville, PA 17241. |
| Township of Shippensburg | Township Municipal Office, 81 Walnut Bottom Road, Shippensburg, PA 17257. |
| Township of Silver Spring | Silver Spring Township Building, 8 Flowers Drive, Mechanicsburg, PA 17050. |
| Township of Southampton | Southampton Township Municipal Building, 200 Airport Road, Shippensburg, PA 17257. |
| Township of South Middleton | South Middleton Township Municipal Building, 520 Park Drive, Boiling Springs, PA 17007. |

| Community | Community map repository address |
|-----------------------------------|---|
| Township of South Newton | South Newton Township Municipal Building, 11 High Mountain Road, Walnut Bottom, PA 17266. |
| Township of Upper Allen | Upper Allen Township Building, 100 Gettysburg Pike, Mechanicsburg, PA 17055. |
| Township of Upper Frankford | Upper Frankford Township Building, 660 Mohawk Road, Newville, PA 17241. |
| Township of Upper Mifflin | Upper Mifflin Township Municipal Building, 455 Whiskey Run Road, Newville, PA 17241. |
| Township of West Pennsboro | West Pennsboro Township Municipal Building, 2150 Newville Road, Carlisle, PA 17015. |

[FR Doc. 2019–25245 Filed 11–20–19; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2019–0002; Internal Agency Docket No. FEMA–B–1974]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will be finalized on the dates listed in the table below and

revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at <https://msc.fema.gov> for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

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 Map Information eXchange (FMIX) online at https://www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer

of the community as listed in the table below.

The modifications are made pursuant to section 201 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.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, 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. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at <https://msc.fema.gov> for comparison. (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.