prepare such a petition, for a total of 5,280 hours annually.

The regulations also establish a means by which an interested person may request that part or all of a decision by the Commissioner be reconsidered, or that the effective date of an action be stayed or extended. Sections 10.33 and 10.35 establish the content, format, and procedural requirements applicable to such requests and explain that they must be submitted no later than 30 days after the decision involved. The regulations provide alternatively that, for good cause, the Commissioner may permit a petition to be filed after 30 days. The regulations also explain that an interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. According to our records, we have received a total of 12 such requests and we assume it takes respondents an average of 10 hours to prepare.

Section 10.65 covers Agency meetings and correspondence. Interested persons may hold meetings and exchange correspondence with FDA representatives on matters within its jurisdiction by following the instructions and providing the information described in § 10.65. Because FDA maintains other information collections in its inventory that cover specific types of meeting requests, we did not previously include burden that may result from this section. However, to account for burden associated with meeting requests and correspondence generally, we provide an estimate of 2,000 submissions annually under this information collection; we assume one respondent per submission; and we assume each submission requires respondents anywhere between 1 to 10 hours to prepare, including gathering and reviewing the necessary material. We therefore use an average of 5 hours for this estimate and base this estimate on our experience with similar information collection.

Section 10.85, issued under section 701(a) of the FD&C Act, sets forth content, format, and procedural requirements by which an interested person may request an advisory opinion from the Commissioner on a matter of general applicability. The regulation explains that, when making a request, the petitioner must provide a concise statement of the issues and questions on which an opinion is requested, and a full statement of the facts and legal points relevant to the request. Based on Agency data, we estimate 4 such requests are received each year and we assume each request requires 16 hours to prepare, for a total of 64 hours annually.

Section 10.115(f)(3) provides for the public submission of draft guidance documents or topics for development to our Dockets Management Staff. To participate in the development and issuance of guidance documents, the public may elect to submit comment through alternative mechanisms as explained in our Good Guidance Practice regulations under § 10.115. Although most submissions and attendant burden associated with recommendations found in Agency guidance is accounted for in individual information collections associated with a particular product area or regulatory topic, here we are accounting for burden associated with general public submissions as described in § 10.115(f)(3). Based on Agency data, we receive an average of 100 such submissions each year; we assume each submission requires an average of 4 hours to prepare; and therefore calculate a total burden of 400 hours annually.

Regulations in 21 CFR 12.20 (§ 12.20) include information collection associated with requesting a formal evidentiary public hearing, and are issued under section 701(e)(2) of the FD&C Act. The regulations provide instructions for filing objections and requests for a hearing on a regulation or order under § 12.20(d). Objections and requests must be submitted within the time specified in § 12.20(e). Each objection, for which a hearing has been requested, must be separately numbered and specify the provision of the regulation or the proposed order. In addition, each objection must include a detailed description and analysis of the factual information and any other document, with some exceptions, supporting the objection. Failure to include this information constitutes a waiver of the right to a hearing on that objection. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under 21 CFR 12.24 and does not limit the evidence that may be presented if a hearing is granted. We estimate 5 respondents will file a request under the regulation and assume each request requires 20 hours to prepare, for a total of 100 hours annually.

Finally, section 12.45 (21 CFR 12.45), issued under section 701 of the FD&C Act, sets forth content, format, and procedural requirements for any interested person to file a petition to participate in a formal evidentiary hearing, either personally or through a representative. Section 12.45 requires that any person filing a notice of participation state their specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, concerning disclosure of data and information by participants (21 CFR 13.25). In accordance with § 12.45(e) the presiding officer may omit a participant's appearance. Based on our records, we estimate 5 filings under this regulation and assume it requires 3 hours to prepare, for a total of 15 hours annually.

Respondents to the information collection are those interested persons conducting business with the FDA, and thus subject to the applicable administrative regulations.

The burden estimates for this collection of information are based on Agency records and our experience over the past 3 years. By revising the information collection to include additional provisions, we have increased our annual burden estimate by 869 responses and 1,096 hours.

Dated: January 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00151 Filed 1–8–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Meeting of the the Substance Abuse and Mental Health Services Administration's National Advisory Council

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given of the meeting on January 28, 2020, of the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Advisory Council (SAMHSA NAC). The meeting is open to the public and can also be accessed remotely. Agenda with call-in information will be posted on the SAMHSA website prior to the meeting at: *https://www.samhsa.gov/about-us/advisory-councils/meetings.* The meeting will include remarks and dialogue from the Assistant Secretary for Mental Health and Substance Use; updates from the

SAMHSA Centers Directors, and a council discussion on clinical trends and emerging national issues with SAMHSA NAC members.

DATES: January 28, 2020, 9:00 a.m. to approximately 4:00 p.m. (ET)/Open.

ADDRESSES: The meeting will be held at SAMHSA Headquarters, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Carlos Castillo, Committee Management Officer and Designated Federal Official, SAMHSA National Advisory Council, 5600 Fishers Lane, Rockville, Maryland 20857 (mail), Telephone: (240) 276–2787, Email: *carlos.castillo@samhsa.hhs.gov*.

SUPPLEMENTARY INFORMATION: The SAMHSA NAC was established to advise the Secretary, Department of Health and Human Services (HHS), and the Assistant Secretary for Mental Health and Substance Use, SAMHSA, to improve the provision of treatments and related services to individuals with respect to substance use and to improve prevention services, promote mental health, and protect legal rights of individuals with mental illness and individuals who are substance users.

Interested persons may present data, information, or views orally or in writing, on issues pending before the Council. Written submissions must be forwarded to the contact person by January 21, 2020. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations must notify the contact person by January 21, 2020. Up to 3 minutes will be allotted for each presentation, and as time permits.

To obtain the call-in number, access code, and/or web access link; submit written or brief oral comments; or request special accommodations for persons with disabilities, please register on-line at: *http://nac.samhsa.gov/Registration/meetingsRegistration.aspx,* or communicate with SAMHSA's Committee Management Officer, CAPT Carlos Castillo.

Meeting information and a roster of Council members may be obtained either by accessing the SAMHSA Council's website at *http://www.samhsa.gov/about-us/advisory-councils/* or by contacting Carlos Castillo.

Council Name: Substance Abuse and Mental Health Services Administration National Advisory Council.

Dated: January 6, 2020.

Carlos Castillo,

Committee Management Officer, SAMHSA.

[FR Doc. 2020–00171 Filed 1–8–20; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2020–0002; Internal Agency Docket No. FEMA–B–2001]

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 April 8, 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–2001, 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