approximately 800 hours (see table 1, row 1).

Under the draft guidance, a recipient of a waiver, exception, or exemption should notify FDA whenever there is a material change in the circumstances that were the basis for the relief. In addition, FDA intends to biennially review waivers, exceptions, and exemptions that are longer than 2 years in duration as described in the draft guidance, and may ask the recipients to submit information to determine whether there has been a material change in the circumstances.

FDA estimates that annually it will receive approximately 1 notification or other information from approximately 1 respondent that there has or has not been a material change in the circumstances that warranted the waiver, exception, or exemption, and that each notification will take approximately 16 hours to prepare and submit to FDA. We estimate that the total annual burden hours for submitting this information to FDA are approximately 16 hours (see table 1, row 2).

Under the draft guidance, a trading partner may request that FDA renew a waiver, exception, or exemption that is of limited duration. This request should include a detailed statement justifying the continuance of the relief and the desired length of the extension. FDA estimates that annually it will receive approximately 1 renewal request from approximately 1 respondent, and that each request will take approximately 16 hours to prepare and submit to FDA. We estimate that the total annual burden hours for submitting these requests to FDA are approximately 16 hours (see table 1, row 3).

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Waivers, Exceptions, and Exemptions from section 582 of the FD&C Act—Draft Guidance	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests to FDA for a Waiver, Exception, or Exemption	20	1	20	40	800
Notification to FDA of a Material Change in Circumstances Warranting the Waiver, Exception, or Exemption	1	1	1	16	16
Requests to FDA to Renew a Waiver, Exception, or Exemption	1	1	1	16	16
Total					832

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

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *https://www.regulations.gov.*

Dated: May 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

National Advisory Council on the National Health Service Corps; Notice of Meeting

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Advisory Committee meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the National Advisory Council of the National Health Service Corps (NACNHSC) will hold a public meeting.

DATES: Tuesday, May 15, 2018, 2:00 p.m. to 5:30 p.m. ET.

ADDRESSES: The meeting is a teleconference and webinar. The conference call-in number is 1–800–619–2521; passcode: 9271697. The webinar link is *https://hrsa.connectsolutions.com/nacnhsc.*

FOR FURTHER INFORMATION CONTACT: Diane Fabiyi-King, Designated Federal Official (DFO), Division of National Health Service Corps (NHSC), Bureau of Health Workforce (BHW), HRSA. Address: 5600 Fishers Lane, Room 14N110, Rockville, Maryland 20857; phone: (301) 443–3609; or email: *DFabiyi-King@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Background: NACNHSC consults, advises, and makes recommendations to the Secretary of HHS and HRSA's Administrator, with respect to their responsibilities under Subpart II, Part D of Title III of the Public Health Service Act, as amended (NHSC and Health Professional Shortage Area Designations). The NACNHSC also reviews and comments on regulations promulgated by the Secretary under Subpart II.

Agenda: During the May 15, 2018, meeting, NACNHSC will discuss issues related to current focus areas of the NHSC. Information about the NACNHSC, a roster of members, the meeting agenda, as well as past meeting summaries is located on the NACNHSC website: *https://nhsc.hrsa.gov/corpsexperience/aboutus/nationaladvisorycouncil/.*

Public Participation: Members of the public and interested parties may request to participate in the meeting or provide oral public comment during the meeting by contacting Monica-Tia Bullock via email at *MBullock@hrsa.gov* by May 10, 2018. Public comment will be limited to three (3) minutes per speaker.

Public participants may also submit written statements in advance of the scheduled meeting. Written statements are due to Monica-Tia Bullock at *MBullock@hrsa.gov* by May 10, 2018. Please be advised that committee members will receive copies of all written statements submitted from the public. Any further public participation will be at the sole discretion of the Chair, with approval from the DFO.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–09825 Filed 5–8–18; 8:45 am]

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