

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹—Continued

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Purchasing controls—820.50(a)	24,738	1	24,738	22	544,236
Purchasing data—820.50(b)	24,738	1	24,738	6	148,428
Identification—820.60	24,738	1	24,738	1	24,738
Traceability—820.65	24,738	1	24,738	1	24,738
Production and process controls—820.70(a)	24,738	1	24,738	2	49,476
Production and process changes and environmental control—820.70(b) and (c)	24,738	1	24,738	2	49,476
Personnel—820.70(d)	24,738	1	24,738	3	74,214
Contamination control—820.70(e)	24,738	1	24,738	2	49,476
Equipment maintenance schedule, inspection, and adjustment—820.70(g)(1)–(g)(3)	24,738	1	24,738	1	24,738
Manufacturing material—820.70(h)	24,738	1	24,738	2	49,476
Automated processes—820.70(i)	24,738	1	24,738	8	197,904
Control of inspection, measuring, and test equipment—820.72(a)	24,738	1	24,738	5	123,690
Calibration procedures, standards, and records—820.72(b)(1)–(b)(2)	24,738	1	24,738	1	24,738
Process validation—820.75(a)	24,738	1	24,738	3	74,214
Validated process parameters, monitoring, control methods, and data—820.75(b)	24,738	1	24,738	1	24,738
Revalidation—820.75(c)	24,738	1	24,738	1	24,738
Acceptance activities—820.80(a)–(e)	24,738	1	24,738	5	123,690
Acceptance status—820.86	24,738	1	24,738	1	24,738
Control of nonconforming product—820.90(a)	24,738	1	24,738	5	123,690
Nonconforming product review/disposition procedures and rework procedures—820.90(b)(1)–(b)(2)	24,738	1	24,738	5	123,690
Procedures for corrective/preventive actions—820.100(a)(1)–(a)(7)	24,738	1	24,738	12	296,856
Corrective/preventive activities—820.100(b)	24,738	1	24,738	1	24,738
Labeling procedures—820.120(b)	24,738	1	24,738	1	24,738
Labeling documentation—820.120(d)	24,738	1	24,738	1	24,738
Device packaging—820.130	24,738	1	24,738	1	24,738
Handling—820.140	24,738	1	24,738	6	148,428
Storage—820.150(a) and (b)	24,738	1	24,738	6	148,428
Distribution procedures and records—820.160(a) and (b) ..	24,738	1	24,738	1	24,738
Installation—820.170	24,738	1	24,738	2	49,476
Record retention period—820.180(b) and (c)	24,738	1	24,738	2	49,476
Device master record—820.181	24,738	1	24,738	1	24,738
Device history record—820.184	24,738	1	24,738	1	24,738
Quality system record—820.186	24,738	1	24,738	1	24,738
Complaint files—820.198(a), (c), and (g)	24,738	1	24,738	5	123,690
Servicing procedures and reports—820.200(a) and (d)	24,738	1	24,738	3	74,214
Statistical techniques procedures and sampling plans—820.250	24,738	1	24,738	1	24,738
Total					8,410,920

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

Dated: September 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21553 Filed 9–7–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Advisory Committee; Oncologic Drugs Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Oncologic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Oncologic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until September 1, 2018.

DATES: Authority for the Oncologic Drugs Advisory Committee will expire on September 1, 2016, unless the

Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT:

Lauren Tesh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, ODAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Oncologic Drugs Advisory Committee. The committee is a discretionary Federal advisory committee established

to provide advice to the Commissioner. The Oncologic Drugs Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 13 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunology oncology, biostatistics, and other related professions. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/ucm107395.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: September 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: National Advisory Council on the National Health Service Corps (NACNHSC).

Dates and Times: September 28, 2016 12:00 p.m.–3:30 p.m. EST.

Place: U.S. Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857, Conference Call Format.

Status: This advisory council meeting will be open to the public.

Purpose: The NACNHSC makes recommendations with respect to their responsibilities under Subpart II, Part D of Title III of the Public Health Service Act, as amended (National Health Service Corps and Health Professional Shortage Area Designations), and shall review and comment upon regulations promulgated by the Secretary under Subpart II.

Agenda: The NACNHSC has concluded its discussion for Fiscal Year 2016 and will present its formal recommendations for each priority area. The Council will discuss policy recommendations for the National Health Service Corps scholarship and loan repayment programs with respect to clinician recruitment and retention in underserved communities throughout the service areas of the NHSC, telehealth, Medication Assisted Treatment (MAT) certification, mentorship, and NHSC discipline expansion, specifically for mental and behavioral, and oral health providers.

The content of the agenda is subject to change prior to the meeting. The NACNHAC final agenda will be available 3 days in advance of the meeting at <http://nhsc.hrsa.gov/corpsexperience/aboutus/nationaladvisorycouncil/meetingsummaries/index.html>.

SUPPLEMENTARY INFORMATION: Further information regarding the NACNHSC, including the roster of members and past meetings summaries, is available at <http://nhsc.hrsa.gov/corpsexperience/aboutus/nationaladvisorycouncil/index.html>. Members of the public and interested parties may request to participate in the meeting by contacting

Monica-Tia Bullock via email at MBullock@hrsa.gov.

- The conference call-in number is 1-800-619-2521. Passcode: 9271697.

- The webinar link is <https://hrsa.connectsolutions.com/nacnhsc>.

Public participants may submit written statements in advance of the scheduled meeting. If you would like to provide oral public comment during the meeting please register with Monica-Tia Bullock at MBullock@hrsa.gov. Public comment will be limited to 3 minutes per speaker. Statements and comments can be addressed to Monica-Tia Bullock by emailing her at MBullock@hrsa.gov.

In addition, please be advised that committee members are given copies of all written statements submitted from the public. Any further public participation will be solely at the discretion of the Chair, with approval of the DFO. Registration through the designated contact for the public comment session is required. Individuals who need reasonable accommodations should contact Monica-Tia Bullock at least 10 days prior to the meeting.

FOR FURTHER INFORMATION CONTACT:

Anyone requesting information regarding the NACNHSC should contact CAPT Jeanean Willis-Marsh, Director, Division of National Health Service Corps, Bureau of Health Workforce, Health Resources and Services Administration, in one of three ways: (1) Send a request to the following address: CAPT Jeanean Willis-Marsh, Director, Division of National Health Service Corps, Bureau of Health Workforce, Health Resources and Services Administration, 5600 Fishers Lane, Room 14N108, Rockville, Maryland 20857; (2) call (301) 443-4494; or (3) send an email to jwillis@hrsa.gov.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Delegation of Authorities

Notice is hereby given that I have delegated to the Commissioner of Food and Drugs (the Commissioner) the authorities vested in the Secretary of the Department of Health and Human Services under sections 102(b)(2), (c); 103(b), (c), (d), (h); 104; 105(b); 106(b), (c); 113(b); 114(d); 115; 201(c); 202(b); 204; 205(b)(2), (c); 206(b); 207(b); 304(b); 305; 306(b); 308; and 309 of the FDA