drug products marketed outside the monograph system.

In the **Federal Register** of June 30, 2021 (86 FR 34759), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section or type of respondent and activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
310.305(c)(5)	3	1	3	1	3
314.80(c)(1)(iii)	5	1	5	1	5
314.80(c)(2)	820	17.32	14,202	60	852,120
Reports of serious adverse drug events (§ 329.100)	285	690	196,650	6	1,179,900
Applicants that have a PSUR waiver for an approved application	55	3.4	187	1	187
Applicants that do not have a PSUR waiver for an approved application	29	2.3	67	2	134
Notifying FDA when normal reporting is not feasible	350	1	350	8	2,800
Total [2]			211,464		2,035,149

[1] The capital costs or operating and maintenance costs associated with this collection of information are approximately $25,000 annually.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section or FD&C act section and activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
310.305	25	1	25	16	400
314.80(j)	352	1,870	658,240	16	10,531,840
Recordkeeping of nonprescription drug adverse event reports (Section 760(e)(1) of the FD&C Act)	300	885.6667	265,700	8	2,125,600
Adding Adverse Event report planning to Continuity of Operations Plans	100	1	100	50	5,000
Maintaining documentation of pandemic conditions and resultant high absenteeism	350	1	350	8	2,800
Maintaining records to identify what reports have been stored and when the reporting process was restored	350	1	350	8	2,800
Total [2]			924,765		12,668,440

[1] There are no capital costs or operating costs associated with this collection of information.
[2] There are maintenance costs of approximately $22,000 annually.

We have increased our estimate to reflect expected adjustments to the information collection since our last submission for OMB review and approval.

Dated: November 1, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24236 Filed 11–4–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1996–D–0405]

Compliance Policy Guide Sec. 110.100; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the withdrawal of Compliance Policy Guide Sec. 110.100, ''Certification for Exports'' (CPG Sec. 110.100), which FDA issued in 1980. We are taking this action because CPG Sec. 110.100 contains information that is either duplicative of other information we have published or no longer reflects the Agency's current thinking.

DATES: The withdrawal is effective November 5, 2021.

FOR FURTHER INFORMATION CONTACT: Tiffany Kelley, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–348–1970, *Tiffany.Kelley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA originally issued CPG Sec. 110.100 on October 1, 1980, in the Agency's Manual of Compliance Policy Guides. The CPG was revised periodically but has not been revised since April 14, 2000.

Since FDA last revised CPG Sec. 110.100, the Agency issued separate guidance for industry on FDA export certification in 2004. FDA revised that guidance in 2005, 2019, and, most recently, in August 2021. The August 2021 version of the guidance for industry, entitled ''FDA Export Certification,'' provides the Agency's current guidance regarding FDA issuance of export certification. Persons with access to the internet may obtain the guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Although this guidance originally complemented the content in CPG Sec. 110.100, changes in the document over time have increasingly resulted in CPG Sec. 110.100 containing duplicative and outdated information. Thus, FDA is withdrawing CPG Sec. 110.100 in its entirety.

Dated: November 1, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24234 Filed 11–4–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Assistant Secretary for Administration; Delegation of Authority

Notice is hereby given that I have amended the delegation of authority to the Assistant Secretary for Preparedness and Response (ASPR); the Director, Centers for Disease Control and Prevention (CDC); the Administrator, Health Resources and Services Administration (HRSA); the Director,

National Institutes of Health (NIH); the Director, Office of Global Affairs (OGA); and the Administrator, Substance Abuse and Mental Health Services Administration (SAMHSA), specifically the authority vested in the Secretary, by section 212(l) of the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (FY19 HHS Appropriations Act) Public Law 115–245, division B, title II, (September 28, 2018), or substantially similar authorities vested in me in the future by Congress, in order to carry out international health activities, including HIV/AIDS and other infectious disease, chronic and environmental disease, and other health activities abroad. Section 212(l) of the FY19 HHS Appropriations Act permits the Secretary of HHS to exercise authority equivalent to that available to the Secretary of State under 22 U.S.C. 2669(c) to award personal services contracts for work performed in foreign countries.

The authority delegated herein includes the authority to determine the necessity of negotiating, executing, and performing such contracts without regard to statutory provisions as related to the negotiation, making, and performance of contracts and performance of work in the United States. This authority is immediately revoked in the event that any subsequent fiscal year HHS appropriations act does not contain the provision currently in section 212(1) or substantially similar authority.

The Director, CDC, may redelegate this authority to the Chief Operating Officer, CDC. This authority may not be further redelegated except as noted above.

The delegatees shall consult with the Secretary of State and relevant Chief of Mission to ensure that this authority is exercised in a manner consistent with section 207 of the Foreign Service Act of 1980 and other applicable statutes administered by the Department of State.

This amended delegation rescinds and supersedes the February 7, 2020, amended delegation concerning this authority. However, all prior redelegations of authority consistent with the content of this memorandum will remain in effect pending further redelegation.

This amended delegation became effective upon date of signature. In addition, I hereby affirm and ratify any actions taken by you or your subordinates which involved the exercise of the authorities delegated herein, or substantially similar authorities vested in me by prior annual HHS appropriations acts, prior to the effective date of the delegation.

Dated: November 2, 2021.

Xavier Becerra,

Secretary.

[FR Doc. 2021–24248 Filed 11–4–21; 8:45 am]

BILLING CODE 4151–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for the treatment of cancer. The outcome of the evaluation will provide information to internal NCI committees that will decide whether NCI should support requests and make available contract resources for development of the potential therapeutic to improve the treatment of various forms of cancer. The research proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; OCT2021 Cycle 39 NExT SEP Committee Meeting.

Date: December 14, 2021,

Time: 9:00 a.m. to 3:00 p.m.

Agenda: To evaluate the NCI Experimental Therapeutics Program Portfolio.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, Room 3A44, Bethesda, Maryland 20892 (WebEx Meeting).

Contact Persons: Barbara Mroczkowski, Ph.D., Executive Secretary, Discovery Experimental Therapeutics Program, National Cancer Institute, NIH, 31 Center Drive, Room 3A44, Bethesda, Maryland 20817, 301–496–4291, *mroczkoskib@mail.nih.gov.*

Toby Hecht, Ph.D., Executive Secretary, Development Experimental Therapeutics Program, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 3W110, Rockville, Maryland 20850, 240–276–5683, *toby.hecht2@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 2, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24237 Filed 11–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel Support for Research Excellence (SuRE) Award (R16).

Date: November 30–December 1, 2021.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Cynthia Louise De La Fuente, Ph.D., Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31, Rockville, MD 20852, 240–669–2740, *delafuentecl@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)