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,