

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Written procedures; 589.2000(e)(1)(iv)	300	1	300	14	4,200

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

We base our estimate of the number of recordkeepers on inspectional data. Based on a review of the information collection since our last request for OMB approval we have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. Review of our inspection data suggests that the number of facilities that need to conduct these separation practices is gradually decreasing, therefore we have decreased the number of facilities who must comply, as well as the total number of hours needed to comply with this burden.

Dated: January 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2011-N-0742; FDA-2018-N-0180; FDA-2019-N-2854; FDA-2021-N-0515; FDA-2014-N-1960; FDA-2017-D-6069; and FDA-2019-N-3325]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food

and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution	0910-0045	12/31/2024
Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications	0910-0810	12/31/2024
Premarket Tobacco Product Applications and Recordkeeping Requirements	0910-0879	12/31/2024
Postmarketing Adverse Experience Reporting and Recordkeeping	0910-0230	1/31/2025
MedWatch: Adverse Event and Product Experience Reporting System (Paper Based)	0910-0291	1/31/2025
De Novo Classification Process (Evaluation of Automatic Class III Designation)	0910-0844	1/31/2025
Laboratory Accreditation for Analyses of Foods	0910-0898	1/31/2025

Dated: January 20, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Biodefense Science Board

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Biodefense Science Board (NBSB or the Board) is authorized under Section 319M of the

Public Health Service (PHS) Act, as added by Section 402 of the Pandemic and All-Hazards Preparedness Act of 2006 and amended by Section 404 of the Pandemic and All-Hazards Preparedness Reauthorization Act. The Board is governed by the Federal Advisory Committee Act, which sets forth standards for the formation and use of advisory committees. The NBSB provides expert advice and guidance on scientific, technical, and other matters of special interest to the Department of Health and Human Services (HHS) regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. Authority to manage and operate the NBSB, including to receive advice and

recommendations from the Board, has been delegated by the Secretary of HHS to the Assistant Secretary for Preparedness and Response (ASPR). The NBSB will meet in public (virtually) on March 7, 2022, beginning at 12:30 p.m. Eastern time. ASPR invites stakeholders and the general public to attend and participate as appropriate. A detailed agenda and instructions to register to attend the meeting will be available on the NBSB meeting website <https://www.phe.gov/nbsb>.

Procedures for Public Participation: Members of the public may attend the meeting via a toll-free phone number or Zoom teleconference, which requires pre-registration. The meeting link to pre-register will be posted on the meeting website <https://www.phe.gov/>