



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2011-N-0742; FDA-2018-N-1967; FDA-2018-N-2970; FDA-2017-N-1779; FDA-2008-N-0500; FDA-2012-N-0129; FDA-2009-D-0268; FDA-2014-D-0609; and FDA-2011-N-0776]

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. Mizrachi, 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	12/31/2021
Biosimilar User Fee Program	0910-0718	12/31/2021
Surveys and Interviews with Investigational New Drug Sponsors to Assess Current Communication Practices with FDA Review Staff Under the Sixth Authorization of the Prescription Drug User Fee Act	0910-0863	12/31/2021
Disclosures of Descriptive Presentations in Professional Oncology Prescription Drug Promotion	0910-0864	12/31/2021
Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products	0910-0572	1/31/2022
General Licensing Provisions; Section 351(k) Biosimilar Applications	0910-0719	1/31/2022
Labeling of Certain Beers Subject to the Labeling Jurisdiction of the FDA	0910-0728	1/31/2022
Implementation of the Drug Supply Chain Security Act - Identification of Suspect Product and Notification	0910-0806	1/31/2022
Reclassification Petitions for Medical Devices	0910-0138	2/28/2022

Dated: April 10, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019-07467 Filed: 4/15/2019 8:45 am; Publication Date: 4/16/2019]