4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2011-N-0231; FDA-2014-N-0996; FDA-2010-N-0161; FDA-2017-N-5624; FDA-2011-N-0085; FDA-2013-D-0575; and FDA-2016-N-3710]

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, PRAStaff@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 Number	Date Approval Expires
Biological Products--General Records and Postmarket Adverse Experience Reporting	0910-0308	4/30/2021
Guidance for Industry: Fast Track, Drug Development Programs--Designation, Development, and Application Review	0910-0389	4/30/2021
Export Certificates for FDA Regulated Products under U.S.C. Sections 801(e) and 802	0910-0498	4/30/2021
Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling	0910-0624	4/30/2021
Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics	0910-0629	4/30/2021
Guidance of Industry: Expedited Programs for Serious Conditions--Drugs and Biologics	0910-0765	4/30/2021
Evaluation of the Food and Drug Administration's Point-of-Sale Campaign	0910-0851	4/30/2021

Dated: June 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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