4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2014-N-0075; FDA-2011-N-0015; FDA-2011-N-0076; FDA-2017-N-0932; FDA-2016-N-4487; FDA-2014-N-0345; FDA-2013-N-0523; FDA-2017-N-2428; FDA-2008-N-0312; and FDA-2014-N-1072]

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
Good Laboratory Practice Regulations for Nonclinical Studies	0910-0119	1/31/2021
Orphan Drug Designation Request Form and The Common European Medicines Agency/Food and Drug Administration Form for Orphan Medicinal Product Designation	0910-0167	1/31/2021
Electronic Records: Electronic Signatures	0910-0303	1/31/2021
Experimental Study on Warning Statements for Cigarette Graphic Health Warnings	0910-0848	1/31/2021
Consumer and Healthcare Professional Identification of and Responses to Deceptive Prescription Drug Promotion	0910-0849	1/31/2021
Data to Support Drug Product Communications	0910-0695	2/28/2021
Applications for FDA Approval to Market a New Drug	0910-0001	3/31/2021
Animal Drug Adverse Event Reporting and Recordkeeping	0910-0284	3/31/2021
Extralabel Drug Use in Animals	0910-0325	3/31/2021
Application for Participation in FDA Fellowship Programs	0910-0780	3/31/2021

Dated: April 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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