4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2012-N-0438; FDA-2018-D-1592; FDA-2014-D-2138; FDA-2018-N-0180; FDA-2014-N-1960; FDA-2015-N-1837; and FDA-2016-D-4308]

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 No.	Date Approval Expires
Recommendations for Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use	0910-0583	10/31/2021
Guidance for Industry on Controlled Correspondence Related to Generic Drug Development	0910-0797	10/31/2021
Guidance for Industry on Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act	0910-0800	10/31/2021
Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications	0910-0810	10/31/2021
MedWatch: Adverse Event and Product Experience Reporting System (Paper-Based)	0910-0291	11/30/2021
Electronic User Fee Payment Form Requests	0910-0805	11/30/2021
Labeling of Red Blood Cell Units with Historical Antigen Typing Results	0910-0862	11/30/2021
Postmarketing Adverse Drug Experience Reporting	0910-0230	12/31/2021

Dated: February 5, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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