4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2016-N-2544; FDA-2013-N-0823; FDA-2013-N-0795; FDA-2013-N-1147; FDA-2013-N-1064; FDA-2008-D-0150; FDA-2013-N-0663; FDA-2010-D-0319; FDA-2013-N-0403; FDA-2012-D-0530; FDA-2016-N-0544]

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, 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 §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 http://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
Current Good Manufacturing Practice; Quality System Regulation	0910-0073	1/31/2020
Format and Content Requirements for Over-the-Counter Drug Product Labeling	0910-0340	1/31/2020
Medical Devices; Third Party Review Under FDAMA	0910-0375	1/31/2020
Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition	0910-0541	1/31/2020
Application for Participation in the Medical Device Fellowship Program; Form FDA 3608	0910-0551	1/31/2020
GFI: Hypertension Indication; Drug Labeling for Cardiovascular Outcome Claims	0910-0670	1/31/2020
Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans	0910-0672	1/31/2020
GFI: Dear Health Care Provider Letters; Improving Communication of Important Safety Information	0910-0754	1/31/2020
Protection of Human Subjects: Informed Consent; Institutional Review Boards	0910-0755	1/31/2020
Requests for Feedback on Medical Device Submissions	0910-0756	1/31/2020
National Direct-to-Consumer Advertising Survey	0910-0828	1/31/2020

Dated: May 23, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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