4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2018-N-3138; FDA-2009-N-0232; FDA-2018-N-4465; FDA-2018-N-4206; FDA-2018-N-3758; FDA-2015-D-1163; FDA-2012-N-0559; FDA-2015-N-3815; FDA-2018-N-3353; and FDA-2018-N-2973]

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 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
Experimental Study of an Accelerated Approval Disclosure	0910-0872	6/30/2020
Interstate Shellfish Dealer's Certificate	0910-0021	5/31/2022
Administrative Detention and Banned Medical Devices	0910-0114	5/31/2022
Medical Device User Fee Small Business Qualifications and Certifications	0910-0508	5/31/2022
Individual Patient Expanded Access Applications	0910-0814	5/31/2022
Electronic Forma for Submissions; Promotional labeling and Advertising Materials for Human Prescription Drugs	0910-0870	5/31/2022
Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation	0910-0456	6/30/2022
Electronic Submission of Medical Device Registration and Listing	0910-0625	6/30/2022
Antimicrobial Animal Drug Distribution Reports and Recordkeeping	0910-0659	6/30/2022
Obtaining Information for Evaluating Nominated Bulk Drug Substances for Use in Compounding Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act	0910-0871	6/30/2022

Dated: July 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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