



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2013-N-0375; FDA-2013-N-0370; FDA-2013-N-0134; FDA-2009-N-0511; FDA-1997-N-0020; FDA-2011-N-0902; FDA-2013-N-0662; FDA-2013-N-0450; FDA-2012-N-0477; FDA-2013-N-0519]

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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 |
|--|--------------------|-----------------------|
| Agreement for Shipments of Devices for Sterilization   | 0910-0131          | 9/30/2019             |
| Export of Medical Devices--Foreign Letters of Approval   | 0910-0264          | 9/30/2019             |
| Mammography Facilities, Standards, and Lay Summaries for Patients  | 0910-0309          | 9/30/2019             |
| Medicated Fee Mill License Application   | 0910-0337          | 9/30/2019             |
| Substances Generally Recognized as Safe: Notification Procedure  | 0910-0342          | 9/30/2019             |
| Prescription Drug Product Labeling; Medication Guide Requirements  | 0910-0393          | 9/30/2019             |
| Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed | 0910-0513          | 9/30/2016             |
| Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed   | 0910-0339          | 10/31/2019            |
| Investigational Device Exemptions Reports and Records --21 CFR 812   | 0910-0078          | 11/30/2019            |
| Guidance for Industry on How to Submit Information in Electronic Format to the Center for Veterinary Medicine Using the FDA Electronic Submission Gateway  | 0910-0454          | 11/30/2019            |

Dated: December 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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