

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–N–0424; FDA–2014–N–0192; FDA–2008–N–0094; FDA–2010–N–0062; FDA–2010–N–0588; FDA–2010–N–0110; FDA–2010–N–0493; FDA–2017–N–1095; FDA–2013–D–0349; FDA–2016–N–2683]

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
Temporary Marketing Permit Applications	0910–0133	11/30/2020
Establishing and Maintaining Lists of U.S. Milk Product Manufacturers/Processors with Interest in Exporting	0910–0509	11/30/2020
Channels of Trade Policy for Commodities with Residues of Pesticide Chemicals for Which Tolerances Have been Revoked, Suspended, or Modified by the EPA	0910–0562	11/30/2020
Medical Devices; Exception from General Requirements for Informed Consent	0910–0586	11/30/2020
Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile	0910–0614	11/30/2020
Prescription Drug Advertisements	0910–0686	11/30/2020
Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded	0910–0688	11/30/2020
Electronic Submission of Allegations of Regulatory Misconduct Associated with Medical Devices	0910–0769	11/30/2020
Providing Waiver-Related Materials in Accordance With the Guidance for Industry on Providing Post-Market Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format	0910–0771	11/30/2020
Data To Support Social and Behavioral Research as Used by the Food and Drug Administration	0910–0847	11/30/2020

Dated: February 9, 2018.
Leslie Kux,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2014–E–2362 and FDA–2014–E–2363]

Determination of Regulatory Review Period for Purposes of Patent Extension; SYLVANT

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SYLVANT and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the

extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 16, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 14, 2018. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 16, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of April 16, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).