The number of respondents to be included in each new survey will vary, depending on the nature of the material or message being tested and the target audience. The burden for this information collection extension is proposed to increase by 12,613 hours since the last OMB approval. The burden increase is due to an increase in the number of respondents and the categories of respondents.

Dated: February 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–02852 Filed 2–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0409]

Mallinkrodt Pharmaceuticals LLC; Withdrawal of Approval of an Abbreviated New Drug Application for PEMOLINE Tablets, 18.75 Milligrams, 37.5 Milligrams, and 75 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the approval of abbreviated new drug application (ANDA) 075726 for PEMOLINE Tablets, 18.75 milligrams (mg), 37.5 mg, and 75 mg, held by Mallinkrodt Pharmaceuticals, LLC (Mallinkrodt). Mallinkrodt requested withdrawal of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of February 13, 2018.

FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6262, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION: FDA approved ANDA 075726 for PEMOLINE Tablets, 18.75 mg, 37.5 mg, and 75 mg, on March 30, 2001, for the conditions of use in the labeling of new drug application (NDA) 016832, the reference listed drug on which it relied. However, on October 24, 2005, FDA announced its concern that the overall liver toxicity risk of CYLERT (NDA 016832) and generic pemoline products outweighed the benefits of these products. Mallinkrodt and other holders of approved applications for PEMOLINE products ceased marketing them at that time. Indeed, Mallinkrodt stated in its May 15, 2013, request for withdrawal of approval of ANDA 075726 that it had never manufactured or distributed its product after it received approval of its application.

In the **Federal Register** of October 4, 2016 (81 FR 68427), FDA erroneously included ANDA 075726 in a list of drug applications for which approval was being withdrawn under § 314.150(c) (21 CFR 314.150(c)). In a separate notice published in this issue of the **Federal Register**, FDA corrects that notice to remove ANDA 075726 from the list of applications whose approval was withdrawn under § 314.150(c). In addition, for the reasons discussed above, and pursuant to Mallinkrodt's request, FDA is withdrawing approval of ANDA 075726, and all amendments and supplements thereto, under § 314.150(d). Distribution of PEMOLINE Tablets, 18.75 mg, 37.5 mg, and 75 mg, in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: February 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–02925 Filed 2–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–E–0780]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for VASCEPA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application 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 drug product.

DATES: Anyone with knowledge that any of the dates as published (in 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 13, 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'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for