FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: FDA is seeking public input on the clinical utility and safety concerns associated with the higher range of opioid analgesic dosing (both in terms of higher strength products and higher daily doses) in the outpatient setting. FDA is interested in better understanding current clinical use and situations that may warrant use of higher doses of opioid analgesics. We are also interested in discussing the magnitude and frequency of harms associated with higher doses of opioid analgesics relative to lower doses, as well as optimal strategies for managing these risks while ensuring access to appropriate pain management for patients.

FDA frequently hears from patients and healthcare providers that higher-dose opioid analgesics continue to be a unique and necessary part of effective pain management for some patients. FDA is also cognizant of serious safety concerns associated with both higher strengths and higher daily doses of opioid analgesics, both in patients and in others who may access these drugs. Higher strength products may be more harmful in cases of accidental exposure and overdose and may also be more sought out for misuse and abuse. Along with a number of other factors, a higher daily opioid dose is associated with greater risk of overdose. Concerns have also been raised that higher dose opioid regimens may carry a higher risk of addiction, although robust evidence for a causal relationship is lacking. There is a strong association between higher opioid dose and duration/persistence of opioid analgesic therapy and assessing temporal relationships and independent effects of opioid dose and duration on the risks of both addiction and overdose is challenging. In addition, FDA acknowledges the complex and evolving landscape of the opioid epidemic, with myriad Federal, State, local, and payer efforts to encourage more judicious prescribing of opioid analgesics, and the growing threat of highly lethal illicit opioids.

To better understand both the clinical utility and harms of higher dose opioid analgesics in the current environment, and to discuss the advantages and disadvantages of various potential risk-management strategies, FDA brings these issues to an advisory committee to seek input and advice from the clinical, patient, public health, and research communities.

In particular, FDA seeks to discuss: (1) The current clinical use and situations that may warrant pain management with opioid analgesics at higher product strengths and daily doses, factors influencing prescribing practices, and specific patient populations for whom there may be utility in prescribing these medications at higher doses; (2) the magnitude and frequency of harms associated with opioid analgesics at higher product strengths and daily doses, relative to lower strengths and daily doses, including the role of opioid dose in adverse health outcomes in both patients and in others who may access the drugs (*e.g.,* risk for developing addiction, fatal overdose), the relevance of therapy duration and physical opioid dependence, and risks in different subpopulations (*e.g.,* patients with chronic non-cancer pain, young children, adolescents); and (3) possible FDA interventions and their expected impact on patients and public health more broadly, including, for example, potential effects on prescribing and pain management practices, patient experience and behaviors, and adverse outcomes such as addiction and overdose.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 12:30 p.m. on June 12, 2019. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 17, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 20, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Moon Hee V. Choi (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 24, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08610 Filed 4–26–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–N–2027; FDA–2012–N–0961; FDA–2018–N–3037; FDA–2014–N–1721; FDA–2005–N–0101; FDA–2012–N–0294; FDA–2011–N–0449; FDA–2018–N–3404; FDA–2018–N–3552; and FDA–2018–N–2969]

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 No.	Date approval expires
Survey of Current Manufacturing Practices for the Cosmetic Industry	0910–0867	3/31/2020
Environmental Impact Considerations	0910–0322	2/28/2022
Generic Clearance for Quantitative Testing of the Development of Food and Drug Administration	0910–0865	2/28/2022
Investigational New Drug Regulations	0910–0014	3/31/2022
Prescription Drug User Fee Program	0910–0297	3/31/2022
Food Additives, Food Contact Substance Notification System	0910–0495	3/31/2022
SPF Labeling and Testing Requirements for OTC Sunscreen Products	0910–0717	3/31/2022
Generic Drug User Fee Program	0910–0727	3/31/2022
Experimental Study of Cigarette Warnings	0910–0866	3/31/2022
Assessment of Combination Product Review Practices	0910–0868	3/31/2022

Dated: April 24, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08607 Filed 4–26–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–E–1140]

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

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 YESCARTA 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 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 June 28, 2019. 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 October 28, 2019. 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 June 28, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 28, 2019. 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 information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–E–1140 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; YESCARTA.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your