There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (July through September 2022)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA (410-786-3365).

[FR Doc. 2022–24670 Filed 11–10–22; 8:45 am]
BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2683]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by December 14, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0847. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

OMB Control Number 0910–0847—Extension

This information collection is intended to support FDA-conducted research. Understanding patients, consumers, and healthcare professionals' perceptions and behaviors plays an important role in improving FDA's regulatory decision-making processes and communications that affect various stakeholders. FDA uses the following methods to achieve these goals: (1) individual indepth interviews, (2) general public focus group interviews, (3) intercept interviews, (4) self-administered surveys, (5) gatekeeper surveys, and (6) focus group interviews. These methods serve the narrowly defined need for direct and informal opinion on a specific topic and serve as a qualitative and quantitative research tool having two major purposes:

- Obtaining useful information for the development of variables and measures for formulating the basic objectives of social and behavioral research and
- successfully communicating and addressing behavioral changes with intended audiences to assess the potential effectiveness of FDA communications, behavioral interventions, and other materials.

While FDA will use these methods to test and refine its ideas and help develop communication and behavioral strategies research, the Agency will generally conduct further research before making important decisions (such as adopting new policies and allocating or redirecting significant resources to support these policies).

FDA's Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Office of the

Commissioner, and any other Centers will use this mechanism to test communications and social and behavioral methods about regulated drug products on a variety of subjects related to consumer, patient, or healthcare professional perceptions, beliefs, attitudes, behaviors, and use of drug and biological products and related materials. These subjects include social and behavioral research, decision-making processes, and communication and behavioral change strategies.

Annually, FDA projects about 25 social and behavioral studies using the variety of test methods listed in this document. FDA is revising this burden to account for the number of studies we have received in the last 3 years and to better reflect the scope of the information collection.

In the **Federal Register** of August 10, 2022 (87 FR 48665), FDA published a 60-day notice requesting public comment on the proposed collection of information. Three comments were received. The first comment was not responsive. The second comment requested that participants be informed that participation is voluntary and can withdraw at any time. Prior to beginning the interview and several times throughout, participants are informed that their participation is voluntary and that they can withdraw at any time. We believe no further clarification to the survey instruments are necessary. The third comment expressed concerns regarding the potential misuse of information from the collection. We have previously outlined the scope and purpose of the information collection, and we do not believe further elaboration is necessary. Further, as outlined in the supporting statement, all information collections must be non-controversial, must not retain Personally Identifiable Information, and ''will not be used for substantially informing influential policy decisions.''

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews and Surveys	109,470	1	109,470	0.25 (15 minutes)	27,368

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, our burden estimate for this information collection reflects an overall increase of 35,886 responses with a corresponding increase of 8,972 hours. We attribute this adjustment to an increase in funding and need to obtain additional information in specific areas, particularly substance abuse (for example, opioids and stimulants) and COVID–19. In addition, we attribute the increase in the number of respondents (from 7,298 to 109,470) and decrease in the number of responses per respondent (from 15 to 1) to an inadvertent administrative error reflected in the 60-day notice. These changes, however, do not impact the estimated total annual responses or burden hours.

Dated: November 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–24693 Filed 11–10–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–2271]

Determination of Regulatory Review Period for Purposes of Patent Extension; PREVYMIS IV Solution, New Drug Application 209940

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 PREVYMIS IV Solution, new drug application (NDA) 209940, 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 (see the **SUPPLEMENTARY INFORMATION** section) are incorrect must submit either electronic or written comments and ask for a redetermination by January 13, 2023. 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 May 15, 2023. 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. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 13, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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