an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product TRULICITY (dulaglutide). TRULICITY is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Subsequent to this approval, the USPTO received a patent term restoration application for TRULICITY (U.S. Patent No. 7,452,966) from Eli Lilly and Company, and the USPTO requested FDA’s assistance in determining this patent’s eligibility for patent term restoration. In a letter dated October 15, 2015, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of TRULICITY represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product’s regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for TRULICITY is 3,303 days. Of this time, 2,937 days occurred during the testing phase of the regulatory review period, while 366 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective: September 4, 2005. FDA has verified the applicant’s claim that the date the investigational new drug application became effective was on September 4, 2005.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262): September 18, 2013. The applicant claims September 17, 2013, as the date the biologics license application (BLA) for TRULICITY (BLA 125469) was initially submitted. However, FDA records indicate that BLA 125469 was submitted on September 18, 2013.

3. The date the application was approved: September 18, 2014. FDA has verified the applicant’s claim that BLA 125469 was approved on September 18, 2014. This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,249 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see DATES). 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. To meet its burden, the petition must be timely (see DATES) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30. Submit petitions electronically to https://www.regulations.gov at Docket No. FDA—2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: December 14, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–30399 Filed 12–16–16; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


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, 11601 Landsdown St., North Bethesda, MD 20852, 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

<table>
<thead>
<tr>
<th>Title of collection</th>
<th>OMB control No.</th>
<th>Date approval expires</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bar Code Label Requirements for Human Drug Products and Biological Products</td>
<td>0910–0537</td>
<td>9/30/2019</td>
</tr>
<tr>
<td>Clinical Laboratory Improvement Amendments Waiver Applications</td>
<td>0910–0598</td>
<td>9/30/2019</td>
</tr>
<tr>
<td>Current Good Manufacturing Practices for Positron Emission Tomography Drugs</td>
<td>0910–0667</td>
<td>9/30/2019</td>
</tr>
<tr>
<td></td>
<td>0910–0746</td>
<td>9/30/2019</td>
</tr>
</tbody>
</table>
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute Of Allergy And Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID Peer Review Meeting.

Date: January 9, 2017.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Ann Marie M. Cruz, Ph.D., Scientific Review Officer, Program Management & Operations Branch DEA/SRP RM 3E71, National Institutes of Health, NIAID, 5601 Fishers Lane, Rockville, MD 20852, 301–761–3100, AnnMarie.Cruz@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Repository Contract Review.

Date: January 5, 2017.

Time: 10:30 a.m. to 1:45 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 2 Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7353, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, annrdm@extra.niddk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: December 13, 2016.

David Clary,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–30364 Filed 12–16–16; 8:45 am]
BILLING CODE 4140–01–P