additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks 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 drug 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 drug product TRADJENTA (linagliptin). TRADJENTA 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 Patent and Trademark Office received a patent term restoration application for TRADJENTA (U.S. Patent No. 7,407,955) from Boehringer Ingelheim Pharma GmbH & Co. KGA, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 10, 2012, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of TRADJENTA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for TRADJENTA is 2,051 days. Of this time, 1,746 days occurred during the testing phase of the regulatory review period, while 305 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 (the FD&C Act) (21 U.S.C. 355(i)) became effective:* September 21, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 21, 2005.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* July 2, 2010. FDA has verified the applicant's claim that the new drug application (NDA) for TRADJENTA (NDA 201–280) was submitted on July 2, 2010.

3. *The date the application was approved:* May 2, 2011. FDA has verified the applicant's claim that NDA 201–280 was approved on May 2, 2011.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 629 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 14, 2014. 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 November 10, 2014. To meet its burden, the petition must 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.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–10945 Filed 5–12–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Council on Blood Stem Cell Transplantation.

Date and Time: May 29, 2014, 10:00 a.m. to 4:00 p.m. (Eastern Standard Time).

Place: The meeting will be via audio conference call and Adobe Connect Pro.

Status: The meeting will be open to the public.

Purpose: Pursuant to Public Law 109–129, 42 U.S.C. 274k (section 379 of the Public Health Service Act, as amended), the Advisory Council on Blood Stem Cell Transplantation (ACBSCT) advises the Secretary of the Department of Health and Human Services and the Administrator, Health Resources and Services Administration on matters related to the activities of the C.W. Bill Young Cell Transplantation Program (Program) and the National Cord Blood Inventory Program.

Agenda: The Council will hear reports from ACBSCT Work Groups including: Cord Blood Thawing and Washing; Access to Transplantation; and Advancing Hematopoietic Stem Cell Transplantation for Hemoglobinopathies. The Council also will hear presentations and discussions on topics including: Accreditation; Adverse Event Reporting; and Unmet Need. Agenda items are subject to changes as priorities indicate.

After Council discussions, members of the public will have an opportunity to provide comments. Because of the Council's full agenda and the time frame in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACBSCT meeting. Meeting summary notes will be posted on the Program Web site at *http://bloodcell.transplant.hrsa.gov/ABOUT/Advisory_Council/index.html.*

The draft meeting agenda will be posted on *www.blsmeetings.net/ACBSCT.* Those participating in this meeting should register by visiting *www.blsmeetings.net/ACBSCT.* The deadline to register for this meeting is Wednesday, May 28, 2014. For all logistical questions and concerns, please contact Anita Allen, Seamon Corporation, by calling (301) 658–3442

or by sending an email to *aallen@seamoncorporation.com*.

The public can join the meeting by:

1. (Audio Portion) Calling the conference number at 888–324–4391 and providing the Participant Code 2426; AND

2. (Visual Portion) Connecting to the ACBSCT Adobe Connect Pro Meeting using the following URL and entering as GUEST: *https://hrsa.connectsolutions.com/acbsct_2/* (copy and paste the link into your browser if it does not work directly, and enter as a guest).

Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: *https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm* and get a quick overview by following URL: *http://www.adobe.com/go/connectpro_overview*. Call (301) 443–0437 or send an email to ptongele@hrsa.gov if you are having trouble connecting to the meeting site.

Public Comment: It is preferred that persons interested in providing an oral presentation submit a written request, along with a copy of their presentation to: Passy Tongele, MBA, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, Room 8W27A, 5600 Fishers Lane, Rockville, Maryland 20857 or email at *ptongele@hrsa.gov*. Requests should contain the name, address, telephone number, email address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative.

The allocation of time may be adjusted to accommodate the level of expressed interest. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may request at the time of the public comment period. Public participation and ability to comment will be limited to time as it permits.

FOR FURTHER INFORMATION CONTACT: Patricia Stroup, MBA, MPA, Executive Secretary, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 11C–06Q, Rockville, Maryland 20857; telephone (301) 443–1127.

Dated: May 7, 2014.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2014–10965 Filed 5–12–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request Return: Chimpanzee Research Use Form (OD)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), Office of the Director (OD), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: The Division of Program Coordination, Planning, and Strategic Initiatives, OD, NIH, Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892; or call non-toll-free number 301–402–9852; or email your request, including your address, to *dpcpsi@od.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Chimpanzee Research Use Form, 0925–NEW, Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this form is to obtain information needed by the NIH to assess whether the proposed research triggers consideration by the Chimpanzee Research Use Panel (CRUP) and the NIH Council of Councils (Council), and if so, whether the research satisfies the agency's policy for research involving chimpanzees. The CRUP is a working group of the Council that has been charged with considering whether research proposing to use chimpanzees is consistent with principles and criteria for research involving chimpanzees, as discussed in the 2011 Institute of Medicine report, *Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity,* and as implemented through agency policy. The NIH, the CRUP, and/or the Council, will consider the information submitted through this form prior to the agency making funding decisions or otherwise allowing the research to begin. Completion of this form is a mandatory step toward receiving NIH support or approval for research involving chimpanzees.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours is 40.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Chimpanzee Research Use Form	Research Community	20	1	2	40