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 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 CERDELGA (eliglustat). CERDELGA is indicated for the long-term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers, intermediate metabolizers, or poor metabolizers as detected by an FDA-cleared test. Subsequent to this approval, the USPTO received a patent term restoration application for CERDELGA (U.S. Patent No. 7,196,205) from Genzyme Corporation, 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 drug product had undergone a regulatory review period and that the approval of CERDELGA 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 CERDELGA is 3,854 days. Of this time, 3,520 days occurred during the testing phase of the regulatory review period, while 334 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:* February 1, 2004. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on February 1, 2004.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* September 20, 2013. FDA has verified the applicant's claim that the new drug application (NDA) for CERDELGA (NDA 205494) was initially submitted on September 20, 2013.

3. *The date the application was approved:* August 19, 2014. FDA has verified the applicant's claim that NDA 205494 was approved on August 19, 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 1,518 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: November 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–28045 Filed 11–21–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Written Comments on the Mid-Course Review Working Group Draft Report and Draft Recommendations for Consideration by the National Vaccine Advisory Committee

AGENCY: National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The National Vaccine Advisory Committee (NVAC) was established in 1987 to comply with Title XXI of the Public Health Service Act (Pub. L. 99–660) (section 2105) (42 U.S. Code 300aa–5). Its purpose is to advise and make recommendations to the Director of the National Vaccine Program on matters related to program responsibilities. The Assistant Secretary for Health (ASH) has been designated by the Secretary of Health and Human Services (HHS) as the Director of the National Vaccine Program. The National Vaccine Program Office (NVPO) is located within the Office of the Assistant Secretary for Health (OASH), Office of the Secretary, U.S. Department of Health and Human Services (HHS). NVPO provides leadership and fosters collaboration among the various Federal agencies involved in vaccine and immunization activities. The NVPO also supports the National Vaccine Advisory Committee (NVAC). The NVAC advises and makes recommendations to the ASH in her capacity as the Director of the National Vaccine Program on matters related to vaccine program responsibilities.

Recognizing the changes in the immunization landscape, the ASH charged the NVAC to conduct a Mid-course review to evaluate the progress of the National Vaccine Plan and provide recommendations to optimize priority areas. In March 2016, the NVAC formed the Mid-Course Review Working Group. Through a series of conference calls, electronic communication, and public discussions during the NVAC meetings, the working group identified a number of draft recommendations for consideration by the NVAC. These recommendations serve as a useful tool in refining collective strategies for shaping the future of the U.S. immunization enterprise, both domestically and globally. The draft report and draft recommendations from the working group will inform NVAC deliberations as the NVAC finalizes their recommendations for transmittal to the ASH.

On behalf of NVAC, NVPO is soliciting public comment on the draft report and draft recommendations from a variety of stakeholders, including the general public, for consideration by the NVAC as they develop their final recommendations to the ASH. It is anticipated that the draft report and draft recommendations, as revised with consideration given to public comment and stakeholder input, will be presented to the NVAC for adoption in February 2017 at the quarterly NVAC meeting.

DATES: Comments for consideration by the NVAC should be received no later than 5 p.m. EDT on December 27, 2016.

ADDRESSES:

- The draft report and draft recommendations are available on the Web at *http://www.hhs.gov/nvpo/nvac/index.html.*

• Electronic responses are preferred and may be addressed to: *anju.abraham@hhs.gov.*

• Written responses should be addressed to: National Vaccine Program Office, U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 733G.3B, Washington, DC 20201, *Attn:* NVAC Mid-course Review c/o Anju Abraham.

FOR FURTHER INFORMATION CONTACT: Anju Abraham, MS, MPH, National Vaccine Program Office, Office of the Assistant Secretary for Health, Department of Health and Human Services; telephone 202–205–5641; email *anju.abraham@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Public health represents a collaboration of multiple sectors in society working together to prevent disease and promote health. These concerted efforts include the tremendous impacts of the U.S. vaccine and immunization system, which represents one of the most significant public health achievements in the 20th century. Estimates suggest that routine childhood immunizations prevented 322 million illnesses and averted 732,000 premature deaths from vaccine-preventable illnesses in children born between 1994–2013, with an estimated societal cost-savings of $1.38 trillion.

The 2010 National Vaccine Plan provides a ten-year strategic direction for all U.S. vaccine and immunization related activities to create a robust and coordinated system to improve the health of Americans by achieving optimal prevention of infectious diseases through vaccination. The Department of Health and Human Services recognized the need to conduct an evaluation of the plan and subsequently charged the National Vaccine Advisory Committee with making recommendations that would address the progress of the 2010 National Vaccine Plan.

In March 2016, the NVAC formed a Mid-Course Review Working Group (MCRWG) to evaluate the status of progress on the goals of the National Vaccine Plan (the document can be found here: *www.hhs.gov/nvpo/national-vaccine-plan/midcourse/index.html*) and develop recommendations to the ASH. The MCRWG began their efforts by reviewing and assessing the findings from the National Vaccine Program's (NVPO) Mid-course Review to identify the opportunity areas. Then, the MCRWG shifted its focus to coordinate additional information collection from non-federal stakeholders to represent consumer groups and from federal stakeholders to further inform their findings and recommendations. Through a number of conference calls, electronic communication, and public discussions at the NVAC meetings, the working group identified a number of draft recommendations. These recommendations frame the five areas that represent opportunities to advance the National Vaccine Program over the remaining five years of the National Vaccine Plan. These five areas of opportunity include:

(1) Strengthen health information and surveillance systems to track, analyze and visualize disease, immunization coverage, and safety data, both domestically and globally;

(2) Foster and facilitate efforts to strengthen confidence in vaccines and the immunization system to increase coverage rates across the lifespan;

(3) Eliminate financial and systems barriers for providers and consumers to facilitate access to routinely recommended vaccines;

(4) Strengthen the science base for the development and licensure of vaccines;

(5) Facilitate vaccine development.

The NVAC draft report outlines the background and rationale for each of the opportunity areas and addresses the challenges, characteristics that constitute success, metrics to measure each area, and proposed metrics to be developed in the future. The conclusions and recommendations detail how the ASH can support HHS activities in these areas.

II. Request for Comment

NVPO, on behalf of the NVAC Mid-course Review Working Group, requests input on the draft report and draft recommendations. In addition to general comments on the draft report and draft recommendations, NVPO is seeking input on characteristics of success, challenges, and metrics to achieve success in the five opportunity areas outlined in the report. Please limit your comments to six (6) pages.

III. Potential Responders

HHS invites input from a broad range of stakeholders including individuals and organizations that have interests U.S. vaccine and immunization efforts and the role of HHS in advancing those efforts.

Examples of potential responders include, but are not limited to, the following:

—General public;

—advocacy groups, non-profit organizations, and public interest organizations;

—academics, professional societies, and healthcare organizations;

—public health officials and immunization program managers;

—physician and non-physician providers that administer immunization services, including pharmacists; and

—representatives from the private sector.

When responding, please self-identify with any of the above or other categories (include all that apply) and your name. Anonymous submissions will not be considered. Written submissions should not exceed six (6) pages. Please do not send proprietary, commercial, financial, business, confidential, trade secret, or personal information.

Dated: November 10, 2016.

Bruce Gellin,

Executive Secretary, National Vaccine Advisory Committee, Deputy Assistant Secretary for Health, Director, National Vaccine Program Office.

[FR Doc. 2016–28090 Filed 11–21–16; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102–3.65(a), notice is hereby given that the Charter for the National Cancer Institute Council of Research Advocates was renewed for an additional two-year period on August 17, 2016.

It is determined that the National Cancer Institute Council of Research Advocates is in the public interest in connection with the performance of duties imposed on the National Cancer Institute and National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

Inquiries may be directed to Jennifer Spaeth, Director, Office of Federal, Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496–2123, or *spaethj@od.nih.gov.*

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–28041 Filed 11–21–16; 8:45 am]

BILLING CODE 4140–01–P