person with an approved or pending drug product application he will be subject to civil money penalties. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Hargrave during his period of debarment.

Any application by Dr. Hargrave for termination of debarment under section 306(d) of the FD&C Act should be identified with Docket No. FDA–2010–N–0299 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain documents in the Docket at *http://www.regulations.gov/.*

Dated: February 24, 2015.

Stephen Ostroff,

Director, Office of the Chief Scientist.

[FR Doc. 2015–05046 Filed 3–4–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0586]

Clinical Trial Imaging Endpoint Process Standards; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Clinical Trial Imaging Endpoint Process Standards.'' This guidance assists sponsors in optimizing the quality of imaging data obtained in clinical trials intended to support approval of drugs and biological products. This guidance focuses on imaging acquisition, display, archiving, and interpretation process standards that FDA regards as important when imaging is used to assess a trial's primary endpoint or a component of that endpoint. This draft guidance revises the draft guidance entitled ''Standards for Clinical Trial Imaging Endpoints'' issued on August 19, 2011.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 4, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Louis Marzella, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5406, Silver Spring, MD 20993–0002, 301–796–1414; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Trial Imaging Endpoint Process Standards.'' The purpose of this guidance is to assist sponsors in optimizing the quality of imaging data obtained in clinical trials intended to support approval of drugs and biological products. It focuses on imaging acquisition, display, archiving, and interpretation standards that FDA regards as important when imaging is used to assess the trial's primary endpoint or a component of that endpoint. The guidance describes the minimum standards a sponsor should use to help ensure that clinical trial imaging data are obtained in a manner that complies with a trial's protocol, maintains imaging data quality, and provides a verifiable record of the imaging process.

This guidance addresses the background considerations for determining the role of imaging in a clinical trial as well as the major considerations in the development of an imaging charter that describes the trial's imaging methods. The guidance specifically addresses the technical components of a charter's description of the image acquisition, image interpretation, and image data development methods.

This draft guidance revises the draft guidance entitled ''Standards for Clinical Trial Imaging Endpoints'' issued on August 19, 2011 (76 FR 51993). Comments we received on the draft guidance have been considered and the guidance has been revised as follows: (1) It has been made clear that the guidance pertains to imaging in clinical trials intended to support approval of drugs and biological products and focuses upon standards that FDA regards as important when imaging is used to assess a trial's primary endpoint; (2) it has been made clear that the imaging charter can be either a single document or an ensemble of documents, depending on multiple factors; (3) it is emphasized that imaging risks are best described in the clinical protocol and should be addressed in consent documents instead of including this information in the imaging charter; (4) it has been emphasized that this guidance does not address whether imaging outcomes are clinically meaningful and are acceptable for drug approval evidence; (5) it has been noted that image acquisition phantoms may or may not be necessary, depending on the nature of the imaging in a clinical trial; (6) it has been modified to emphasize the need for the clinical protocol (not the charter) to describe how incidental findings will be handled; (7) it has been noted that the charter should identify any use of investigational equipment (for international trials, the guidance encourages use of equipment that is lawfully marketed in the area); and (8) a section has been added that describes the importance of having the clinical trial sponsor ensure the fidelity of all charter components with the clinical protocol.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the major considerations for standardization of imaging primary endpoints in clinical trials of drugs and biological products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be

used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: February 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–05016 Filed 3–4–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Written Comments on the Draft National Adult Immunization Plan; Extension of Comment Period

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

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS), through the National Vaccine Program Office (NVPO) is extending the public comment period for a draft document titled ''The National Adult Immunization Plan (NAIP).'' The availability of that draft document was published in the **Federal Register** on February 6, 2015, Volume 80, Number 25, pages 6721–6722.

DATES: The comment period is extended by 14 days and thus will end on March 23, 2015.

ADDRESSES: (1) The draft NAIP is available on the Web at *www.hhs.gov/nvpo/.*

(2) Electronic responses are preferred and may be addressed to: *Rebecca.Fish@hhs.gov.*

(3) Written responses should be addressed to: National Vaccine Program Office, U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 733G, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Rebecca Fish, National Vaccine Program Office, Office of the Assistant Secretary for Health, Department of Health and Human Services; telephone (202) 260–9283; fax (202) 260–1165; email: *Rebecca.Fish@hhs.gov.*

SUPPLEMENTARY INFORMATION: The notice of availability of the draft National Adult Immunization Plan (NAIP) was published in the **Federal Register** on February 6, 2015, Volume 80, Number 25, pages 6721–6722, with a deadline for comments of March 9, 2015. The NAIP is a national plan that will require engagement from a wide range of stakeholders to achieve its full vision. The plan emphasizes collaboration and prioritization of efforts that will have the greatest impact. NVPO is soliciting public comment on the draft NAIP from a variety of stakeholders, including the general public, for consideration as they develop their final report to the Secretary. Since the notice of availability and draft guidance documents were published, the Department has received requests to extend the comment period to allow sufficient time for a full review of the draft NAIP. NVPO is committed to affording the public a meaningful opportunity to comment on the draft NAIP and welcomes comments.

Persons with access to the Internet may obtain the draft National Adult Immunization Plan on NVPO's Web site at *http://www.hhs.gov/nvpo.*

Dated: February 25, 2015.

Bruce Gellin,

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

[FR Doc. 2015–05030 Filed 3–4–15; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.

The meetings 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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Gene Regulation.

Date: February 26, 2015.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Richard A Currie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1108, MSC 7890, Bethesda, MD 20892, (301) 435–1219, *currieri@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Biomaterials.

Date: March 5–6, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Joseph D Mosca, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5158, MSC 7808, Bethesda, MD 20892, (301) 435–2344, *moscajos@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)