across different financing and delivery models (e.g., managed care and fee-for-service) and population groups (e.g., beneficiaries with physical, mental or both physical and mental disabilities, dually eligible beneficiaries, all other beneficiaries). The survey will serve as baseline information on the experiences of low-income adults during the early stages of implementation of the Affordable Care Act provision that permits states to expand eligibility to adults with income below 138 percent of the federal poverty level who were not previously eligible. Along with states, we can use the survey information as one indicator of the quality of care within and across states. It also will be used to assist us along with the states in efforts to provide better care and more affordable care to Medicaid beneficiaries. *Form Number:* CMS–10493 (OCN: 0938–New); *Frequency:* Once; *Affected Public:* Individuals and households; *Number of Respondents:* 1,500,000; *Total Annual Responses:* 510,000. *Total Annual Hours:* 170,000. (For policy questions regarding this collection contact Marsha Lillie-Blanton at 410–786–8856.).

2. *Type of Information Collection Request:* New collection (request for a new OMB control number); *Title of Information Collection:* Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments; *Use:* Section 6002 of the Affordable Care Act added section 1128G to the Social Security Act (Act), which requires applicable manufacturers and applicable group purchasing organizations (GPOs) of covered drugs, devices, biologicals, or medical supplies to report annually to CMS certain payments or other transfers of value to physicians and teaching hospitals, as well as, certain information regarding the ownership or investment interests held by physicians or their immediate family members in applicable manufacturers or applicable GPOs.

Specifically, applicable manufacturers of covered drugs, devices, biologicals, and medical supplies are required to submit on an annual basis the information required in section 1128G(a)(1) of the Act about certain payments or other transfers of value made to physicians and teaching hospitals (collectively called covered recipients) during the course of the preceding calendar year. Similarly, section 1128G(a)(2) of the Act requires applicable manufacturers and applicable GPOs to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. Applicable manufacturers must report the required payment and other transfer of value information annually to CMS in an electronic format. The statute also provides that applicable manufacturers and applicable GPOs must report annually to CMS the required information about physician ownership and investment interests, including information on any payments or other transfers of value provided to physician owners or investors, in an electronic format by the same date. Applicable manufacturers and applicable GPOs are subject to civil monetary penalties (CMPs) for failing to comply with the reporting requirements of the statute. We are required by statute to publish the reported data on a public Web site. The data must be downloadable, easily searchable, and aggregated. In addition, we must submit annual reports to the Congress and each state summarizing the data reported. Finally, section 1128G of the Act generally preempts state laws that require disclosure of the same type of information by manufacturers.

We published a final rule in 2013 to implement this program, which included several information collections subject to the Paperwork Reduction Act. This information collection request is to inform the public about information collected that is necessary for registration, attestation, dispute resolution and corrections, record retention, and submitting an assumptions document within Open Payments. *Form Number:* CMS–10495 (OCN: 0938–New); *Frequency:* Once; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 451,582; *Total Annual Responses:* 451,582. *Total Annual Hours:* 949,005. (For policy questions regarding this collection contact Melissa Heesters at 410–786–0618.).

Dated: July 16, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–17476 Filed 7–19–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0838]

Compliance Policy Guide Sec. 253.100—Use of Units of Plasma and Fresh Frozen Plasma Which Have Been Thawed; Withdrawal of Compliance Policy Guide

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of the compliance policy guide (CPG) entitled ''Sec. 253.100—Use of Units of Plasma and Fresh Frozen Plasma Which Have Been Thawed,'' issued October 1, 1980, and revised in March 1995.

DATES: The withdrawal is effective July 22, 2013.

FOR FURTHER INFORMATION CONTACT: Robert L. Hummel, Medical Products and Tobacco Policy Staff, Office of Policy and Risk Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–4510.

SUPPLEMENTARY INFORMATION: FDA issued the CPG entitled ''Sec. 253.100—Use of Units of Plasma and Fresh Frozen Plasma Which Have Been Thawed'' on October 1, 1980, and revised it in March 1995. FDA originally issued CPG Sec. 253.100 to provide FDA's current thinking regarding the time limits for when thawed frozen plasma should be used for transfusion. At the time of issuance of the CPG, 21 CFR 606.122(m)(3) provided that the instruction circular shall include, when applicable, instructions to begin administration of the product within 6 hours after thawing. The CPG noted a planned regulatory change that would allow greater flexibility in the time of administration requirements for frozen plasma products.

In a final rule published in the **Federal Register** on January 3, 2012 (77 FR 7), with an effective date of July 2, 2012, FDA modified the time limits contained in the instruction circular for when administration of thawed frozen plasma products begins, as required by 21 CFR 606.122(m)(3), to ''within a specified time after thawing.'' As noted in the preamble to the final rule, the change was made ''to provide industry with increased flexibility for developing and specifying timeframes for which thawed plasma components can still be used for transfusion if stored at

appropriate temperatures per industry standards.'' (See 77 FR 7 at 14). With this regulatory change, CPG Sec. 253.100 is obsolete.

FDA is therefore withdrawing CPG 253.100, in its entirety, to eliminate the obsolete compliance policy.

Dated: July 16, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–17531 Filed 7–19–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Synergizing Efforts in Standards Development for Cellular Therapies and Regenerative Medicine Products; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), is announcing a public workshop entitled ''Synergizing Efforts in Standards Development for Cellular Therapies and Regenerative Medicine Products.'' The purpose of the public workshop is to bring together a broad range of stakeholders to discuss current and future standards development activities involving cellular therapies and regenerative medicine products.

Date and Time: The public workshop will be held on October 7, 2013, from 8:30 a.m. to 4:30 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. Please visit the following Web site for location, parking, security, and travel information: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Person: Sherri Revell, Center for Biologics Evaluation and Research (HFM–49), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–2000, FAX: 301–827–3079, email: *CBERPublicEvents@fda.hhs.gov* (Subject line: SESDCTRMP Workshop).

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, and fax numbers) to Sherri Revell (see *Contact Person*) or email to *CBERPublicEvents@fda.hhs.gov* (Subject line: SESDCTRMP Workshop Registration) by September 23, 2013. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

Streaming Webcast of the Public Workshop: For those unable to attend in person, FDA will Webcast the public workshop. To join the Webcast of the public workshop, please go to: *https://collaboration.fda.gov/sesdctrmpworkshop/.* If you have never attended an Adobe Connect meeting before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* Get a quick overview: *http://www.adobe.com/go/connectpro_overview.* Registration is not required for those attending via Adobe Connect.

If you need special accommodations due to a disability, please contact Sherri Revell (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

Standardization efforts concerning the clinical development of cellular therapies and regenerative medicine products have generated a great deal of interest. These efforts include standards development, expert opinion position papers, and professional practice guidelines. However, relatively little is done to coordinate the various existing efforts. In the public workshop, FDA hopes to bring together a broad range of stakeholders of cellular therapies and regenerative medicine products in order to:

- Inform stakeholders about the types of standards and standards organizations that are available currently, the role that the Federal Agencies play in standards development, and the potential role that stakeholders can play in standards development.
- Provide a high-level overview of current standards development activities in the fields of cellular therapy and regenerative medicine and the regulatory application of standards.
- Provide opportunity for discussion of areas of high interest for current or future standards development in the fields of cellular therapy and regenerative medicine and to explore ways to minimize redundancy and maximize collaboration.

We encourage all who have an interest in the development of cellular therapies and regenerative medicine products to attend the public workshop.

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at: *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm.* Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: July 16, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–17528 Filed 7–19–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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 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; Developmental Brain Disorders.

Date: July 23, 2013.

Time: 11:00 a.m. to 12:00 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: Pat Manos, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, 301–408–9866, *manospa@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;