2011, with a 180-day approval period. Written comments and recommendations will be considered from the public if received by the individuals designated below by May 4, 2011.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/regulations/pra* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below by May 4, 2011.

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

3. *By Facsimile or E-mail to OMB.* OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer. *Fax Number:* (202) 395–6974. *E-mail: OIRA_submission@omb.eop.gov.*

Dated: April 1, 2011.

Michelle Shortt,

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

[FR Doc. 2011–8459 Filed 4–7–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0544]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Application for Participation in the Medical Device Fellowship Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Application for Participation in the Medical Device Fellowship Program" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@FDA.HHS.GOV*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 27, 2011 (76 FR 4913), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0551. The approval expires on March 31, 2014. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: April 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–8369 Filed 4–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program: Statement of Reasons for Not Conducting Rule-Making Proceedings

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In accordance with section 2114(c)(2)(B) of the Public Health Service Act, notice is hereby given of the reasons for not conducting a rule-making proceeding for adding Guillain-Barré Syndrome (GBS) to the Vaccine Injury Table at this time.

DATES: Written comments are not being solicited.

FOR FURTHER INFORMATION CONTACT: Geoffrey Evans, M.D., Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), Room 11C–26, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone number (301) 443–6593.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660 (42 U.S.C. 300aa–10 *et seq.*) established the National Vaccine Injury Compensation Program (VICP) for persons found to be injured by vaccines. Under this Federal program, petitions for compensation are filed with the United States Court of Federal Claims (Court). The Court, acting through special masters, makes findings as to eligibility for, and amount of, compensation. In order to gain entitlement to compensation under title XXI of the Public Health Service (PHS) Act for a covered vaccine, a petitioner must establish a vaccine-related injury or death, either by proving that the first symptom of an injury/condition, as defined by the Qualifications and Aids to Interpretation, occurred within the time period listed on the Vaccine Injury Table (Table), and therefore presumed to be caused by a vaccine (unless another cause is found), or by proof of vaccine causation, if the injury/condition is not on the Table or did not occur within the time period specified on the Table.

The statute authorizing the VICP provides for the inclusion of additional vaccines in the VICP when they are recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children. See section 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa–14(e)(2). Consistent with section 13632(a)(3) of Public Law 103–66, the regulations governing the VICP provide that such vaccines will be included in the Table as of the effective date of an excise tax to provide funds for the payment of compensation with respect to such vaccines. 42 CFR 100.3(c)(5). The statute authorizing the VICP also authorizes the Secretary to create and modify a list of injuries,

disabilities, illnesses, conditions, and deaths (and their associated time frames) associated with each category of vaccines included on the Table. See sections 2114(c) and 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa–14(c) and 30aa–14(e)(2). Finally, section 2114(c)(2) of the PHS Act, 42 U.S.C. 300aa–14(c)(2) provides that:

[a]ny person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

(A) receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission, whichever occurs first, the Secretary shall conduct a rule-making proceeding on the matters proposed in the petition or publish in the **Federal Register** a statement of reasons for not conducting such proceeding.

On September 9, 2010, a private person submitted a petition to amend the Table. This petition was submitted to the Chief Special Master, Sandra Lord, with a copy to Dr. Geoffrey Evans, Director, Division of Vaccine Injury Compensation. Pursuant to the VICP statute, Dr. Evans referred the petition to the Commission on October 28, 2010. The Commission discussed the petition at its meeting on March 3, 2011. At the conclusion of this discussion, the Commission voted unanimously to recommend that the Secretary not proceed with rule-making to amend the Table as requested in the petition.

The petition requests that the Secretary amend the Table to include Guillain-Barré Syndrome (GBS) as an injury following certain vaccines. The petition asserts that "[e]very drug company admits that GBS is linked to many different vaccines including influenza, meningitis, and cervical cancer [human papillomavirus]." The petitioner asserts that her mother received the seasonal influenza vaccine, and was subsequently diagnosed with GBS. Other than the assertion cited, the petition does not cite scientific support, nor indicate specifically for which vaccines GBS should be added as an injury, nor indicate any appropriate time-frame.

Nonetheless, the Secretary takes very seriously proposals to modify the Table. Prior to receipt of the petition, in 2008, the Secretary contracted with the Institute of Medicine (IOM) to review the epidemiological, clinical, and biological evidence regarding adverse health events associated with specific vaccines covered by the VICP. The vaccines to be reviewed are:

- Varicella vaccines,
- influenza vaccines,
- hepatitis B vaccine,
- human papillomavirus vaccines,
- hepatitis A vaccines,
- meningococcal vaccines,
- measles-mumps rubella vaccines, and
- diphtheria, tetanus, pertussis vaccines.

The IOM committee will author a consensus report with conclusions on the evidence bearing on causality and the evidence regarding the biological mechanisms that underlie specific theories for how a specific vaccine is related to a specific adverse event. In particular, the report will contain updated findings on the possible causal relationship between certain VICP-covered vaccines and GBS, as well as other possible injuries/medical conditions. The Secretary expects to receive the IOM consensus report in early summer. After receipt of the consensus report, and a careful analysis of the important scientific and policy considerations raised by the findings in the report, the Secretary will consider whether to engage in a rule-making proceeding to modify the Table. As required by law, any such rule-making proceeding would include notice and opportunity for a public hearing and at least 180 days of public comment. See section 2114(c)(1) of the PHS Act, 42 U.S.C. 300aa–14(c)(1). Also as required by law, the Secretary would provide to the Commission a copy of the proposed regulation or revision, request recommendations and comments by the Commission, and afford the Commission at least 90 days to make such recommendations. See section 2114(d) of the PHS Act, 42 U.S.C. 300aa–14(d).

The Secretary intends to consider whether to engage in a rule-making process with the benefit of the important scientific information soon to be provided by the IOM; to begin the lengthy process without such additional information would not result in rule-making founded on the best and most recent scientific knowledge. For these reasons, it has been determined not to conduct a rule-making proceeding based on the petition received at this time.

Dated: April 1, 2011.

Mary K. Wakefield,

Administrator.

[FR Doc. 2011–8395 Filed 4–7–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; 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 Center for Scientific Review Advisory Council (CSRAC), formerly National Institutes of Health Peer Review Committee, was renewed for an additional two-year period on March 31, 2011.

It is determined that the CSRAC is in the public interest in connection with the performance of duties imposed on the 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.*

Dated: April 4, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–8440 Filed 4–7–11; 8:45 am]

BILLING CODE 4140–01–P

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 grant applications and/or contract proposals 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 and/or 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