

*FoodborneIllnessContaminants/Metals/UCM352467.pdf*).

4. U.S. Food and Drug Administration, "Analytical Results from Inorganic Arsenic in Rice Cereals for Infants, Non-rice Infant Cereal and Other Foods Commonly Eaten by Infants and Toddlers," 2016, (<http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm485278.htm>).

5. U.S. Food and Drug Administration, "Arsenic in Rice and Rice Products Risk Assessment: Report," 2016, (<http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm485278.htm>).

6. U.S. Food and Drug Administration, "External Peer Review Report. Arsenic in Rice and Rice Products Risk Assessment: Draft Report, Addendum, and Model," 2015, (<http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM486544.pdf>).

7. U.S. Food and Drug Administration, "FDA's Response to External Peer Review on FDA's Arsenic in Rice and Rice Products Risk Assessment: Draft Report (July 2015), Addendum to FDA's Arsenic in Rice and Rice Products Risk Assessment, and Arsenic in Rice and Rice Products Risk Assessment Cancer Model," 2016, (<http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM487230.pdf>).

Dated: April 1, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-07840 Filed 4-5-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0001]

#### Endocrinologic and Metabolic Drugs Advisory Committee; Amendment of Notice

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an amendment to the notice of a meeting of the Endocrinologic and Metabolic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of March 17, 2016. The amendment is being made to reflect a change in the *Date and Time* portion of the document. The *Date* of the meeting is changed to May 24, 2016. There are no other changes.

**FOR FURTHER INFORMATION CONTACT:** LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533,

[EMDAC@fda.hhs.gov](mailto:EMDAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of March 17, 2016 (81 FR 14448), FDA announced that a meeting of the Endocrinologic and Metabolic Drugs Advisory Committee would be held on May 25, 2016. On page 14449, in the first column, the *Date and Time* portion of the document is changed to read as follows:

*Date and Time:* The meeting will be held on May 24, 2016, from 8 a.m. to 5 p.m.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: April 1, 2016.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2016-07906 Filed 4-5-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0001]

#### Advisory Committee; Bone, Reproductive and Urologic Drugs Advisory Committee, Renewal

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; renewal of advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the renewal of the Bone, Reproductive and Urologic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Bone, Reproductive and Urologic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until March 23, 2018.

**DATES:** Authority for the Bone, Reproductive and Urologic Drugs Advisory Committee will expire on March 23, 2018, unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:** Kalyani Bhatt, Division of Advisory Committee and Consultant Management, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, email: [BRUDAC@fda.hhs.gov](mailto:BRUDAC@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Bone, Reproductive and Urologic Drugs Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Bone, Reproductive and Urologic Drugs Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug products for use in the practice of osteoporosis and metabolic bone disease, obstetrics, gynecology, urology and related specialties, and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of osteoporosis and metabolic bone disease, obstetrics, gynecology, urology, pediatrics, epidemiology, or statistics and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/ucm107572.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION**

**CONTACT).** In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: April 1, 2016.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2016-07908 Filed 4-5-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Vaccine Injury Compensation Program; List of Petitions Received

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

**FOR FURTHER INFORMATION CONTACT:** For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place NW., Washington, DC 20005, (202) 357-6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857; (301) 443-6593, or visit our Web site at: <http://www.hrsa.gov/vaccinecompensation/index.html>.

**SUPPLEMENTARY INFORMATION:** The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa-10 *et seq.*, provides that those seeking

compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa-12(b)(2), requires that “[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register.**” Set forth below is a list of petitions received by HRSA on February 1, 2016, through February 29, 2016. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master “shall afford all interested persons an opportunity to submit relevant, written information” relating to the following:

1. The existence of evidence “that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,” and

2. Any allegation in a petition that the petitioner either:

a. “[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by” one of the vaccines referred to in the Table, or

b. “[S]ustained, or had significantly aggravated, any illness, disability, injury, or

condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine” referred to in the Table.

In accordance with Section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading “**FOR FURTHER INFORMATION CONTACT**”), with a copy to HRSA addressed to Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, 5600 Fishers Lane, 08N146B, Rockville, MD 20857. The Court's caption (Petitioner's Name v. Secretary of Health and Human Services) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

Dated: March 28, 2016.

**James Macrae,**

*Acting Administrator.*

#### List of Petitions Filed

1. Tessa Skrypek on behalf of D. S., Chippewa Falls, Wisconsin, Court of Federal Claims No: 16-0146V
2. Brandie Sanders, Cypress, Texas, Court of Federal Claims No: 16-0147V
3. Taylor K. Frady on behalf of A. F., Deceased, Piermont, New York, Court of Federal Claims No: 16-0148V
4. Robert Kern, Lower Gwynedd, Pennsylvania, Court of Federal Claims No: 16-0150V
5. Katherine R. Hime, South Bend, Indiana, Court of Federal Claims No: 16-0151V
6. Emma Hicks, Madison, Wisconsin, Court of Federal Claims No: 16-0153V
7. Christina Garber, Honolulu, Hawaii, Court of Federal Claims No: 16-0154V
8. Joseph T. Renfroe, Hiram, Georgia, Court of Federal Claims No: 16-0156V
9. Hannah Mackie, Chicago, Illinois, Court of Federal Claims No: 16-0157V
10. Laura McClary, Sacramento, California, Court of Federal Claims No: 16-0158V