

measures (e.g., padded brassieres and analgesics). In infrequent patients, symptoms of pain and tenderness may be severe enough to warrant treatment by suppression of ovarian function. DANOCRINE is usually effective in decreasing nodularity, pain, and tenderness. It should be stressed to the patient that this treatment is not innocuous in that it involves considerable alterations of hormone levels and that recurrence of symptoms is very common after cessation of therapy.”

DANOCRINE (danazol) Capsules, 50 mg, 100 mg, and 200 mg, were discontinued from sale in December 2004. FDA moved the product to the “Discontinued Drug Product List” section of the Orange Book at that time. In a letter dated October 17, 2011, Sanofi-Aventis requested the withdrawal of the DANOCRINE application. On July 19, 2013, the Agency issued a **Federal Register** notice withdrawing NDA 017557, the application for DANOCRINE, effective August 19, 2013.

After reviewing our records and based on the information we have at this time, FDA has determined that under § 314.161 DANOCRINE (danazol) Capsules, 50 mg, 100 mg, and 200 mg, were not withdrawn from sale for reasons of safety or effectiveness, except with respect to the indication for fibrocystic breast disease. Fibrocystic breast disease refers to mastalgia or breast pain caused by benign proliferative breast tissue. The term fibrocystic breast disease is no longer used, in part because it is not accurate to describe the condition as a disease when it is in fact the result of normal physiologic changes.

DANOCRINE (danazol) has been associated with two serious adverse reactions: hepatocellular injury (i.e., hepatocellular injury, hepatocellular jaundice, and hepatic failure) and an increased risk of rhabdomyolysis in patients taking danazol and statins. These two adverse reactions were not yet recognized when DANOCRINE (danazol) was originally approved for fibrocystic breast disease in 1980. Both of these adverse reactions were added to the safety labeling for the product several years after the product was initially approved. In addition, androgenic adverse effects and a contraindication for use in women who are pregnant or attempting to become pregnant limit the utility of DANOCRINE (danazol) for the fibrocystic breast disease indication.

The Agency conducted a review of the benefit-risk profile for each indication of DANOCRINE (danazol). For the

treatment of fibrocystic breast disease, the Agency concluded that the benefit-risk profile of the product is unfavorable given the risk of potentially serious adverse reactions and that the condition is a benign, non-disease state. In addition, many other treatment options exist for this condition, including dietary measures, use of supportive undergarments and pain relievers such as acetaminophen or non-steroidal anti-inflammatory drug products. Many of these treatment options present a very low risk of adverse reactions. For the indications of treatment of endometriosis amenable to hormone management and prevention of attacks of angioedema of all types (cutaneous, abdominal, and laryngeal) in males and females, the Agency has determined that DANOCRINE (danazol) continues to have a favorable benefit-risk profile.

Accordingly, the Agency will continue to list DANOCRINE (danazol) Capsules, 50 mg, 100 mg, and 200 mg, in the “Discontinued Drug Product List” section of the Orange Book. All approved ANDAs have removed the fibrocystic breast disease indication from their labeling. In addition, FDA will continue to approve ANDAs that refer to DANOCRINE (danazol) Capsules as long as they meet relevant legal and regulatory requirements, but FDA will not accept or approve ANDAs that refer to this drug product and propose to include the fibrocystic breast disease indication.

Dated: August 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-18081 Filed 8-21-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Training in Primary Care Medicine and Dentistry

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD) will hold a public meeting. Information about ACTPCMD and the agenda for this meeting can be found on the ACTPCMD website at: <https://www.hrsa.gov/advisory-committees/primarycare-dentist/index.html>.

DATES: September 10, 2018, 9:00 a.m.–5:00 p.m. ET, and September 11, 2018, 8:30 a.m.–2:30 p.m. ET.

ADDRESSES: This meeting will be held in person and offer virtual access through teleconference and webinar. The address for the meeting is 5600 Fishers Lane, Rockville, Maryland 20857.

- *Conference call-in number:* 1-800-238-9007; Passcode: 532320.

- *Webinar link:* <https://hrsa.connectsolutions.com/actpcmd>.

FOR FURTHER INFORMATION CONTACT: Dr. Kennita Carter, Designated Federal Official (DFO), Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, 15N-116, Rockville, Maryland 20857; 301-945-3505; or KCarter@hrsa.gov.

SUPPLEMENTARY INFORMATION:

ACTPCMD provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under section 747 of Title VII of the Public Health Service (PHS) Act, as it existed upon the enactment of Section 749 of the PHS Act in 1998. ACTPCMD prepares an annual report describing the activities of the Committee, including findings and recommendations made by the Committee concerning the activities under section 747, as well as training programs in oral health and dentistry. The annual report is submitted to the Secretary and Chairman and ranking members of the Senate Committee on Health, Education, Labor and Pensions, and the House of Representatives Committee on Energy and Commerce. The Committee also develops, publishes, and implements performance measures and guidelines for longitudinal evaluations of programs authorized under Title VII, Part C, of the PHS Act, and recommends appropriation levels for programs under this Part.

During the September 10–11, 2018, meeting, ACTPCMD will have follow-up discussions on PHS Act section 747 and oral health training programs, and finalize its recommendations on funding and appropriation levels to be included in its 16th report. In addition, the Committee will complete the 16th report and a pending report on promoting clinical trainee and faculty well-being and mitigating burnout. Agenda items are subject to change as priorities dictate.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested

and may be limited as time allows. Requests to make oral comments or submit a written statement to ACTPCMD should be sent to Dr. Kennita R. Carter, DFO, using the contact information above at least 3 business days prior to the meeting.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Dr. Kennita R. Carter at the address and phone number listed above at least 10 business days prior to the meeting. Since this meeting occurs in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 10 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018-18074 Filed 8-21-18; 8:45 am]

BILLING CODE 4165-15-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 (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS 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 Lisa L. Reyes, Clerk of Court, 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 website 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 July 1, 2018, through July 31, 2018. 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: August 16, 2018.

George Sigounas,
Administrator.

List of Petitions Filed

1. Gregory Jackson, Stevensville, Maryland, Court of Federal Claims No: 18-0949V
2. Debra D. Nicholson, West Baden, Indiana, Court of Federal Claims No: 18-0953V
3. Deborah Spivey, Carthage, Tennessee, Court of Federal Claims No: 18-0959V
4. Shauna Rhyne and Cody Rhyne on behalf of C. R., Grand Junction, Colorado, Court of Federal Claims No: 18-0961V
5. Chris Skye and Lesley Skye on behalf of D. S., Novato, California, Court of Federal Claims No: 18-0962V