

TABLE 1—APPLICATIONS FOR WHICH WITHDRAWAL OF APPROVAL HAS BEEN REQUESTED—Continued

| Application No. | Drug product(s) | Applicant or holder |
|-------------------|--|---|
| ANDA 040336 | Acetaminophen, Butalbital, and Caffeine Tablets, 500 mg/50 mg/40 mg. | Do. |
| ANDA 040688 | Acetaminophen, Caffeine, and Dihydrocodeine Bitartrate Capsules, 356.4 mg/30 mg/16 mg. | WraSer Pharmaceuticals LLC, 121 Marketridge Dr., Ridgeland, MS 39157. |

Therefore, under § 314.150(d), and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner of Food and Drugs, approval of the applications for the drug products listed in table 1 of this document, and all amendments and supplements thereto, is withdrawn (see **DATES**). Distribution of these products in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

The safety issue discussed in this document and the January 14, 2011, **Federal Register** document is limited to products containing more than 325 mg of acetaminophen per dosage unit. Thus, the withdrawal of approval of products containing more than 325 mg of acetaminophen per dosage unit listed in table 1 does not change the approval status of any products with 325 mg or less of acetaminophen per dosage unit that were approved under the same application. In addition, the withdrawal of approval of products containing more than 325 mg of acetaminophen per dosage unit does not change the approval status of products with 325 mg or less of acetaminophen per dosage unit that refer to or rely on the withdrawn products. For example, this withdrawal action will not affect the approval status of an ANDA for a product that contains 325 mg or less per dosage unit that references a product listed in table 1, but for which FDA approved a suitability petition for a lower strength under section 505(j)(2)(C) of the FD&C Act and § 314.93 (21 CFR 314.93)).

Dated: March 24, 2014.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2014-06801 Filed 3-26-14; 8:45 am]

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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 11C-26, Rockville, MD 20857; (301) 443-6593.

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 Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which 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, 2014, through February 28, 2014. 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) “Sustained, 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) “Sustained, 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 Vaccine Injury Compensation Program, Healthcare Systems Bureau, 5600 Fishers Lane, Room 11C-26, 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 20, 2014.

Mary K. Wakefield,
Administrator.

List of Petitions Filed

1. Douglas Fischer, Englewood, New Jersey, Court of Federal Claims No: 14-0096V
2. Robert Petrucelli, Meriden, Connecticut, Court of Federal Claims No: 14-0097V
3. Michael Greenberg, Key Biscayne, Florida, Court of Federal Claims No: 14-0098V
4. Suzanne Hackett, American Fork, Utah, Court of Federal Claims No: 14-0099V
5. Anil John Kukreja and Michal Kukreja on behalf of David Kukreja, Montclair, New Jersey, Court of Federal Claims No: 14-0104V
6. Elissa Cascio, Salt Lake City, Utah, Court of Federal Claims No: 14-0107V
7. Alexys Hebert, Lafayette, Louisiana, Court of Federal Claims No: 14-0109V
8. Madison and Sarah Lester on behalf of E.M.L., Baraboo, Wisconsin, Court of Federal Claims No: 14-0110V

9. Margaret Hopper, Maywood, Illinois, Court of Federal Claims No: 14-0111V
10. Yvonne Hooper, Houston, Texas, Court of Federal Claims No: 14-0112V
11. Lynn Johnson on behalf of E.J., Birmingham, Alabama, Court of Federal Claims No: 14-0113V
12. Carolyn Mertz, Fullerton, California, Court of Federal Claims No: 14-0114V
13. William Wick, New Martinsville, West Virginia, Court of Federal Claims No: 14-0116V
14. Linda Hutson, Eden, North Carolina, Court of Federal Claims No: 14-0117V
15. Carrin Simmons on behalf of E.S., Jacksonville, Florida, Court of Federal Claims No: 14-0118V
16. Michael Grieshop, Dublin, Ohio, Court of Federal Claims No: 14-0119V
17. Kevin Koen, Hope, Alaska, Court of Federal Claims No: 14-0120V
18. Susan Zalewski, Somers Point, New Jersey, Court of Federal Claims No: 14-0124V
19. Taylor Jenkins, Somers Point, New Jersey, Court of Federal Claims No: 14-0125V
20. Lance Buterbaugh, Woodland Hills, California, Court of Federal Claims No: 14-0127V
21. Debra Passantino, Arlington Heights, Illinois, Court of Federal Claims No: 14-0130V
22. Thomas Craig Self, Madisonville, Tennessee, Court of Federal Claims No: 14-0136V
23. Kenneth H. Barrett and Tammy Barrett on behalf of J.H.B., Deceased, Clyde, North Carolina, Court of Federal Claims No: 14-0137V
24. Paige S. Goodings, Baraboo, Wisconsin, Court of Federal Claims No: 14-0141V
25. Johnny Martin and Anna Martin on behalf of H.D.M., Baraboo, Wisconsin, Court of Federal Claims No: 14-0142V
26. Fay Kennedy, Glenwood Springs, Colorado, Court of Federal Claims No: 14-0144V
27. Maria Kong, New York, New York, Court of Federal Claims No: 14-0145V
28. Vanya Taylor on behalf of Z.T., Joplin, Missouri, Court of Federal Claims No: 14-0146V
29. Elahe Amani, Los Alamitos, California, Court of Federal Claims No: 14-0150V
30. Meghan McSherry, Baraboo, Wisconsin, Court of Federal Claims No: 14-0153V
31. Gene McSherry and Kari McSherry on behalf of Lydia McSherry,

- Baraboo, Wisconsin, Court of Federal Claims No: 14-0154V
32. Brian N. Goldsworthy, Raleigh, North Carolina, Court of Federal Claims No: 14-0157V
33. Frank Fortunato, Simi Valley, California, Court of Federal Claims No: 14-0158V
34. Kelly Johnson, Simi Valley, California, Court of Federal Claims No: 14-0159V
35. Steven Bayless, Phoenix, Arizona, Court of Federal Claims No: 14-0160V
36. Danise Schwartzfigure on behalf of Elijah Schwartzfigure, Fort Leonard Wood, Missouri, Court of Federal Claims No: 14-0161V

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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: National Institute of Child Health and Human Development Special Emphasis Panel.

Date: April 14, 2014.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Marita R. Hopmann, Ph.D., Scientific Review Administrator, Scientific Review Branch, National Institute of Child Health and Human Development, 6100 Building, Room 5B01, Bethesda, MD 20892, (301) 435-6911, hopmannm@mail.nih.gov.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, Pediatric Critical Care and Trauma Scientist Development Program (PCCTSDP).

Date: April 22, 2014.