Passcode: N5v5y*

FOR FURTHER INFORMATION CONTACT: Donna Mendrick, National Center for Toxicological Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2208, Silver Spring, MD 20993–0002, 301–796–8892, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On May 18, 2022, the Science Advisory Board Chair will welcome the participants, and the NCTR Director will provide a Center-wide update on scientific initiatives and accomplishments during the past year. The Science Advisory Board will be presented with an overview of the Science Advisory Board Subcommittee Site Visit Report and a response to this review. The Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Food Safety and Applied Nutrition, Center for Tobacco Products, and the Office of Regulatory Affairs will each briefly discuss their specific research strategic needs and potential areas of collaboration.

On May 19, 2022, there will be updates from the NCTR Research Divisions and a public comment session. Following an open discussion of all the information presented, the open session of the meeting will close so the Science Advisory Board members can discuss personnel issues at NCTR.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

Procedure: On May 18, 2022, from 8 a.m. to 5:55 p.m., Central Standard Time, and May 19, 2022, from 8 a.m. to 11:30 a.m., Central Standard Time, the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 13, 2022. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Central Standard Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 5, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 6, 2022.

Closed Committee Deliberations: On May 19, 2022, from 11:30 a.m. to 12 p.m., Central Standard Time, the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at NCTR.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Donna Mendrick at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08460 Filed 4–19–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1155]

The Use of Published Literature in Support of New Animal Drug Applications; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry #106 entitled ''The Use of Published Literature in Support of New Animal Drug Applications.'' This draft guidance, when finalized, will replace the existing final guidance #106, ''The Use of Published Literature in Support of New Animal Drug Approval,'' which FDA published in August 2000 and which specifically addressed the use of a single article to support drug approval. This revision of the guidance document considers multiple uses of the scientific literature, including narrative reviews, systematic reviews, and meta-analyses to support approval of a new animal drug.

DATES: Submit either electronic or written comments on the draft guidance by June 21, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a

third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–1155 for ''The Use of Published Literature in Support of New Animal Drug Applications.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Amey Adams, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0816, *Amey.Adams@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #106 entitled ''The Use of Published Literature in Support of New Animal Drug Applications.'' The purpose of this document is to provide guidance to animal drug sponsors on specific areas of the approval process where the available scientific literature may be useful to support the approval of a new animal drug application, an abbreviated new animal drug application, or a conditionally approved new animal drug application, as well as methodologies to ensure the validity of conclusions drawn by animal drug sponsors from the scientific literature to support an approval.

The original guidance #106, ''The Use of Published Literature in Support of New Animal Drug Approval,'' was published in 2000 and specifically addressed the use of a single article to support drug approval. Since its publication, animal drug sponsors have used literature to support various aspects of animal drug development and approval, including early stages of drug development, dosage characterization, microbial food safety, design of the target animal safety evaluation, prediction of potential adverse effects, and substantial evidence of effectiveness.

Animal drug sponsors have expressed interest in further leveraging information published in the scientific literature to support new animal drug approvals. Use of published scientific literature is of interest because it makes use of existing knowledge and may reduce the number of animals needed for studies to support approval and, in some cases, may provide greater inferential value compared to individual studies conducted for the purpose of supporting an approval. Scientific literature may also be used to respond to specific regulatory questions, identify data gaps, and inform protocol design. This draft guidance expands upon the original guidance #106 by considering multiple uses of the scientific literature, including narrative reviews, systematic reviews, and meta-analyses to support approval of a new animal drug.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''The Use of Published Literature in Support of New Animal Drug Applications.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in FDA's guidance entitled ''The Use of Published Literature in Support of New Animal Drug Applications'' have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either

https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or *https://www.regulations.gov*.

Dated: April 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08452 Filed 4–19–22; 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 (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 Section 2112(b)(2) of 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, Maryland 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 United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, 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 March 1, 2022, through March 31, 2022. 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 United States 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, Health Systems Bureau, 5600 Fishers Lane, 08N146B, Rockville, Maryland 20857. The Court's caption (*Petitioner's Name* v. *Secretary of HHS*) 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.

Carole Johnson,

Administrator.

List of Petitions Filed

1. Maxwell Manley, Phoenix, Arizona, Court of Federal Claims No: 22–0227V
2. Brendan Bixel, Portland, Oregon, Court of Federal Claims No: 22–0228V
3. Nancy Purcell, Tinley Park, Illinois, Court of Federal Claims No: 22–0231V
4. William Watkins, Norman, Oklahoma, Court of Federal Claims No: 22–0232V
5. Robert Thomson, Woods Cross, Utah, Court of Federal Claims No: 22–0234V
6. Maise Johnson, Springfield, Massachusetts, Court of Federal Claims No: 22–0235V
7. Danae Denton, Chicago, Illinois, Court of Federal Claims No: 22–0238V
8. Khair M. Issa, Woodbridge, Virginia, Court of Federal Claims No: 22–0240V
9. Danielle Poore, Palo Alto, California, Court of Federal Claims No: 22–0241V
10. Margaret Chalgren, Minneapolis, Minnesota, Court of Federal Claims No: 22–0245V
11. Meredith Perry on behalf of L. P., Phoenix, Arizona, Court of Federal Claims No: 22–0246V
12. Teresa Donovan, Seattle, Washington, Court of Federal Claims No: 22–0249V
13. Dana Bertucci on behalf of D. A., Chicago, Illinois, Court of Federal Claims No: 22–0250V
14. Marivic Malolos, Fontana, California, Court of Federal Claims No: 22–0251V
15. Jennifer Goldson and Brian Goldson on behalf of J. G., Phoenix, Arizona, Court of Federal Claims No: 22–0254V
16. Paul E. Saliba, Dallastown, Pennsylvania, Court of Federal Claims No: 22–0257V
17. Myrtle Barrett, Kershaw, South Carolina, Court of Federal Claims No: 22–0258V
18. Stanley Hatch, Goleta, Florida, Court of Federal Claims No: 22–0260V