TABLE 1—STATUS OF DRAFT GUIDANCE Q&AS AND FINAL GUIDANCE Q&AS—Continued

Q&A category	Q&A No.	Previous guidance location	Current guidance location
Part III. Exclusivity	Q.II.3	Final	Final.
	Q.III.1	Final	Final.
	Q.III.2	Final	Final.

*The draft Q&A continues to be available in the New and Revised Draft Q&A Guidance (Revision 3). All other draft Q&As are available in the Additional Draft Q&A Guidance.

This guidance finalizes all but three of the Q&As that were included in the draft guidance ''New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2)'' issued on December 12, 2018. FDA considered comments it received regarding these Q&As, and made changes to the Q&As, as appropriate; for example, providing additional and clearer information in Q.I.16 and providing additional information about text in the labeling for a biosimilar in Q.I.22. FDA also made certain clarifying and editorial changes to update previously finalized Q&As. Editorial changes were made primarily for clarification.

FDA has retained Q.I.12 in draft and transferred it to ''New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 3).'' This draft Q&A addresses how an applicant can demonstrate that its proposed injectable biosimilar product or proposed injectable interchangeable product has the same ''strength'' as the reference product. FDA withdrew Q.I.23, which addressed a process for obtaining certain letters related to reference product access for testing for products with risk evaluation and mitigation strategy with elements to assure safe use. In light of the enactment of the Further Consolidated Appropriations Act, 2020 (FCA Act) (Pub. L. 116–94), which includes provisions related to this topic (see Division N, section 610, of the FCA Act (21 U.S.C. 355–2)), FDA intends to issue guidance describing how the existing process for obtaining these letters is being aligned with the framework set forth in the new law. FDA also withdrew Q.II.1, which addressed the definition of ''protein.'' For information on the definition of ''protein'' in section 351(i)(1) of the PHS Act, see the final rule entitled ''Definition of the Term 'Biological Product' '' (85 FR 10057, February 21, 2020; 21 CFR 600.3(h)(6)).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Questions and Answers on Biosimilar Development and the BPCI Act.'' 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 21 CFR part 312 for submission of an investigational new drug application have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314.50 for submission of a new drug application have been approved under OMB control number 0910–0001. The collections of information in section 351(a) of the PHS Act and 21 CFR part 601 for submission of a biologics license application (BLA) have been approved under OMB control number 0910–0338. The collections of information in section 351(k) of the PHS Act and 21 CFR part 601 for submission of a BLA have been approved under OMB control number 0910–0719.

III. Electronic Access

Persons with access to the internet may obtain the final guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: September 14, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–20255 Filed 9–17–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Council on Migrant Health

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Secretary's National Advisory Council on Migrant Health (NACMH or Council) has scheduled a public meeting. Information about NACMH and the agenda for this meeting can be found on the NACMH website at: *https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/nacmh.*

DATES: November 2–5, 2021; 12:30 p.m.–4:30 p.m. Eastern Time each day.

ADDRESSES: This meeting will be held by webinar. Instructions for joining the meeting will be posted on the NACMH website 30 business days before the meeting date. For meeting information updates, go to the NACMH website at: *https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/nacmh.*

FOR FURTHER INFORMATION CONTACT: Esther Paul, NACMH Designated Federal Officer, Strategic Initiatives and Planning Division, Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–594–4300; or *epaul@hrsa.gov.*

SUPPLEMENTARY INFORMATION: NACMH is a non-discretionary advisory body mandated by the Public Health Service Act, Title 42 U.S.C. 218, to advise, consult with, and make recommendations to the Secretary of the Department of Health and Human Services and the Administrator of HRSA regarding the organization, operation, selection, and funding of migrant health centers and other entities funded under section 330(g) of the Public Health

Service Act (42 U.S.C. 254b). NACMH meets twice each calendar year, or at the discretion of the Designated Federal Officer in consultation with the NACMH Chair.

Agenda items and meeting times are subject to change as priority dictate. The agenda items for the meeting may include topics and issues related to migratory and seasonal agricultural worker health. Refer to the NACMH website listed above for any updated information concerning the meeting. 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 requested and may be limited as time allows. Requests to submit a written statement or make oral comments to the NACMH should be sent to Esther Paul using the contact information above at least 5 business days before the meeting.

Individuals who plan to participate and need special assistance or another reasonable accommodation should notify Esther Paul at the address and phone number listed above at least 10 business days before the meeting. Registration is required to participate in the meeting prior to entry. Registration and meeting attendance instructions will be posted on the NACMH website 30 business days before the meeting date.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–20231 Filed 9–17–21; 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, 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 August 1, 2021, through August 31, 2021. 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, Healthcare 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.

Diana Espinosa,

Acting Administrator.

List of Petitions Filed

1. Hussam Ismael, Orlando, Florida, Court of Federal Claims No: 21–1642V
2. Nicholas D. Goettl, Cincinnati, Ohio, Court of Federal Claims No: 21–1644V
3. Robert Anderson, Vestavia Hills, Alabama, Court of Federal Claims No: 21–1645V