there is a genuine and substantial issue of fact that requires a hearing. If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.*

This notice is issued under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

Dated: August 2, 2024.

Douglas C. Throckmorton,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 2024–17515 Filed 8–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3449]

Office of Pharmaceutical Quality Experiential Learning Site Visit Program; Program Announcement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the Fiscal Year 2025 CDER Office of Pharmaceutical Quality (OPQ) Experiential Learning Site Visit Program (ELSVP). The purpose of this document is to invite pharmaceutical companies interested in participating in this program to submit a site visit proposal to CDER's OPQ.

DATES: Starting October 1, 2024, FDA will accept requests to participate in the ELSVP program.

ADDRESSES: If your facility is interested in offering a site visit, submit either an electronic proposal to *CDEROPQSiteVisits@fda.hhs.gov* or a written proposal to Lyle Canida (see **FOR FURTHER INFORMATION CONTACT**). See the ''III. Site Selection'' and ''IV. Proposals for Participation'' sections of this document for potential priorities onsite selection criteria and how to submit a proposal to participate in the program.

FOR FURTHER INFORMATION CONTACT: Lyle Canida, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. M4522, Silver Spring, MD 20993–0002, 301–796–6825, email: *CDEROPQSiteVisits@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A critical part of the commitment by CDER to assure safe and effective high-quality drugs are available to the American public is gaining an understanding of all aspects of a drug's development and commercial lifecycle, including the variety of drug manufacturing operations. To support this commitment, CDER has initiated various training and development programs, including the FY2025 OPQ ELSVP. This site visit program is designed to offer experiential and firsthand learning opportunities that will provide OPQ staff with a better understanding of the pharmaceutical industry and its operations, as well as the challenges that may impact a drug's developmental program and commercial life cycle. The goal of these visits is to enhance OPQ staff exposure to the drug development and manufacturing processes in industry; therefore, a tour of pharmaceutical company facilities, including manufacturing and laboratory operations, is an integral part of the experience.

II. The Experiential Learning Site Visit Program (ELSVP)

In this site visit program, groups on average of no more than 15 OPQ staff—who have experience in a variety of educational backgrounds, supporting pharmaceutical quality assessment—will observe operations or important aspects of commercial manufacturing, pilot plants (if applicable), and testing over a 1- to 2-day period. To facilitate the learning process for OPQ staff, overview presentations by industry related to drug development, manufacturing, and testing may be included.

CDER encourages companies engaging in the development and manufacturing of both active pharmaceutical ingredients (small and large molecules) and drug products to respond.

OPQ staff participating in this program will benefit by gaining a better understanding of current industry practices, processes, and procedures. Participating sites will have an opportunity to showcase their technologies and their actual manufacturing and testing facilities.

Although observation of all aspects of drug development and production would be beneficial to OPQ staff, the following list identifies a number of areas of particular interest to its staff. The list is not intended to be exhaustive, mutually exclusive, or to limit industry response:

- Drug products:
  - Solutions, suspensions, emulsions, semisolids, and solids
  - Modified- and immediate-release formulations
  - Drug-device combination products regulated by CDER (*e.g.,* inhalation products, transdermal systems, implants intended for drug delivery, and pre-filled syringes)
- Active pharmaceutical ingredients manufactured by:
  - Chemical synthesis
  - Fermentation
  - Biotechnology
- Design, development, manufacturing, and controls:
  - Engineering controls for aseptic processes
  - Novel delivery technologies
  - Hot melt extrusion
  - Soft-gel encapsulation
  - Lyophilization
  - Blow-Fill-Seal packaging
  - Isolators
  - Spray-drying
  - Process analytical technology, measurement systems, and real-time release testing
- Advanced manufacturing technologies:
  - Continuous manufacturing
  - 3-dimensional printing
  - Nanotechnology
- Terminal sterilization:
  - Gamma irradiation
  - PET drug manufacturing and controls
  - Medical gas manufacturing and controls

III. Site Selection

Selection of potential facilities will be based on the priorities developed for OPQ staff training, the facility's current compliance status with FDA, and in consultation with the appropriate FDA district office. All travel expenses associated with this program will be the responsibility of CDER Offices; therefore, the number of sites selected will be based on the availability of funds and resources for the fiscal year. FDA will not provide financial compensation to the pharmaceutical site as part of this program.

IV. Proposals for Participation

Companies interested in offering a site visit or learning more about this site

visit program should respond by submitting a proposal directly to Lyle Canida at *CDEROPQSiteVisits@fda.hhs.gov* (see the **FOR FURTHER INFORMATION CONTACT** sections of this document for more information). To aid in OPQ's site selection and planning, your proposal should include the information below:

- A contact person,
- Site visit location(s),
- Facility Establishment Identifier and D–U–N–S numbers, as applicable,
- Maximum number of FDA staff that can be accommodated during a site visit (maximum of 15, on average),
- A proposed agenda outlining the learning objectives and associated activities for the site visit,
- Maximum number of site visits your site would be willing to host by the close of the Government fiscal year, September 30, 2025, and
- Proposed time frames for each site visit (*i.e.,* month or quarter).

Please note that the requested proposed agenda will be reviewed to determine the educational benefit to OPQ in conducting the visit, and selected sites may be asked to refine the agenda to maximize the educational benefit. After a site is selected, OPQ will communicate with the contact person for the site to determine the actual dates for the visit.

Proposals submitted without this minimum information will not be considered. Based on response rate and type of responses, OPQ may consider alternative pathways to meeting our training goals.

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17640 Filed 8–7–24; 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 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 8W–25A, 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 June 1, 2024, through June 30, 2024. This list provides the name of the petitioner, city, and state of vaccination (if unknown then the city and state of the person or attorney filing the 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, 8W–25A, 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. Patrick Wey, Portland, Oregon, Court of Federal Claims No: 24–0851V