

easily and efficiently elicit and review program feedback. The online voluntary survey will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their experience with the FDA while a Commissioner's Fellow. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of

surveys being misrouted within the Agency mail system. The information gathered by the survey will be used to gain insights into, and to document, impacts that the CFP has had and is having on former CFP fellows and contributions and impacts that the former fellows are making in their current work. The voluntary surveys include questions to assess the

following measures: Post-fellowship employment (*e.g.*, employment type); number of awards; number of contributions while a CFP fellow (*e.g.*, number of publications, guidance documents authored or co-authored); and contributions in their field (*e.g.*, list of publications).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

| Activity                        | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---------------------------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Fellowship Program Survey ..... | 35                    | 1                                  | 35                     | * 0.50                      | 17.5        |

<sup>1</sup> There are no capital costs or operating maintenance costs associated with this collection of information.

\* 30 minutes.

FDA based these estimates on the number of fellows who have graduated and left the Agency over the past 5 years.

Dated: October 24, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2017–N–4180]

#### Voluntary Medical Device Manufacturing and Product Quality Program; Public Workshop; Request for Comments; Reopening of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is reopening the comment period provided in the notice entitled “Voluntary Medical Device Manufacturing and Product Quality Program; Public Workshop; Request for Comments,” published in the **Federal Register** of July 25, 2017 (82 FR 34531). That notice announced the public workshop to be held on October 10, 2017, and requested comments by October 18, 2017. The Agency is taking this action to allow interested parties additional time to submit comments.

**DATES:** FDA is reopening the comment period for the public workshop “Voluntary Medical Device

Manufacturing and Product Quality Program; Public Workshop; Request for Comments” published on July 25, 2017 (82 FR 34531). Submit either electronic or written comments on this public workshop by December 14, 2017.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 14, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of December 14, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### 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–2017–N–4180 for “Voluntary Medical Device Manufacturing and Product Quality Program; Public Workshop; Request for Comments; Reopening of Comment Period.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

- **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.gpo.gov/fdsys/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.

**FOR FURTHER INFORMATION CONTACT:** Francisco Vicenty, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 3426, Silver Spring, MD 20993, 301-796-5577, email: [Francisco.Vicenty@fda.hhs.gov](mailto:Francisco.Vicenty@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 25, 2017 (82 FR 34531), FDA published a notice announcing the public workshop entitled "Voluntary Medical Device Manufacturing and Product Quality Program; Public Workshop; Request for Comments" with an 85-day comment period to request comments. The public workshop was held on October 10, 2017. FDA is reopening the comment period for the public workshop until December 14, 2017. The Agency believes that this will allow adequate time for interested persons to submit comments without significantly delaying the action by the Agency.

Dated: October 24, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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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 (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, Acting 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 08N146B, Rockville, MD 20857; (301) 443-6593, or visit our Web site 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 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 September 1, 2017, through September 30, 2017. 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