the guidance addresses the procedures that apply when a Center seeks civil money penalties; and fourth, the guidance addresses the civil money penalty amounts that may be assessed for: (1) Failing to submit required clinical trial registration and/or results information to the *ClinicalTrials.gov* data bank, (2) knowingly submitting false or misleading clinical trial information to the data bank, (3) failing to submit the required certification to FDA, or (4) knowingly submitting a false certification to FDA.

In the **Federal Register** of September 21, 2018 (83 FR 47926), FDA announced the availability of the draft guidance. FDA received comments on the draft guidance and considered all comments in finalizing this guidance. FDA revised the guidance to clarify that FDA does not intend to include on its Lists of Inspectional Observations, Forms FDA 483, any inspectional observations regarding potential violations relating to the *ClinicalTrials.gov* data bank; however, information that is collected by an investigator regarding potential violations of such requirements will be included in an Establishment Inspection Report and provided to the relevant Center for further evaluation. The guidance has also been revised to make clear that, in determining whether to seek civil money penalties, FDA intends to take into consideration any corrective action taken by a responsible party or submitter after receiving a Notice of Noncompliance. The guidance further explains that FDA intends to post Notices of Noncompliance on its website and to transmit the Notices of Noncompliance to the National Institutes of Health (NIH), so NIH can include the notice regarding noncompliance required under section 402(j)(5)(E) of the PHS Act in the *ClinicalTrials.gov* data bank. The guidance also provides some limited examples of applicable clinical trials of products that potentially may pose a higher risk to human subjects or applicable clinical trials of products intended to address significant public health need. In addition, editorial changes were made to the guidance to improve clarity. The guidance announced in this notice finalizes the draft guidance dated September 21, 2018.

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 civil money penalties relating to the *ClinicalTrials.gov* data bank. 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

This guidance contains no collection 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.

However, this guidance refers to previously approved collections of information. This collection of information is subject to review by OMB under the PRA. The collection of information referenced in this guidance is related to information required under section 402(j)(5)(B) of the PHS Act and has been approved under OMB control number 0910–0616.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: August 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–17909 Filed 8–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0257]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Rapid Response Surveys

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 16, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0500. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food and Drug Administration Rapid Response Surveys

OMB Control Number 0910–0500—Extension

Section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355) requires that important safety information relating to all human prescription drug products be made available to FDA so that the Agency can take appropriate action to protect the public health when necessary. Section 702 of the FD&C Act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the FD&C Act. Under section 519 of the FD&C Act (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device-related deaths, serious injuries, and malfunctions to FDA; to require user facilities to report device-related deaths directly to FDA and to manufacturers; and to report serious injuries to the manufacturer. Section 522 of the FD&C Act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the FD&C Act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health or gross deception of the consumer. Section 1003(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)) authorizes the Commissioner of Food and Drugs to implement general powers (including conducting research) to carry out effectively the mission of FDA.

These sections of the FD&C Act enable FDA to enhance consumer protection from risks associated with medical products usage that are not

foreseen or apparent during the premarket notification and review process. FDA's regulations governing application for Agency approval to market a new drug (21 CFR part 314) and regulations governing biological products (21 CFR part 600) implement these statutory provisions. FDA's regulations governing Agency oversight of Foods, Cosmetics, Dietary Supplements, and Animal Food and Feed (21 CFR parts 70 through 199) also implement these statutory provisions. Currently, FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch reporting systems using Forms FDA 3500 and 3500A (OMB control number 0910–0291), electronic Safety Reporting Portal (OMB control number 0910–0645), and the vaccine adverse event reporting system.

FDA is seeking extension of OMB approval to collect vital information via a series of rapid response surveys. Participation in these surveys will be voluntary. This request covers rapid response surveys for community-based healthcare professionals, general type medical facilities, specialized medical facilities (those known for cardiac surgery, obstetrics/gynecology services, pediatric services, etc.), other healthcare professionals, patients, consumers, and risk managers working in facilities containing products related to or regulated by FDA. FDA will use the information gathered from these surveys to quickly obtain vital information about medical product risks and interventions to reduce risks so the Agency may take appropriate public health or regulatory action including dissemination of this information as necessary and appropriate.

FDA projects six emergency risk related surveys per year with a sample of between 50 and 10,000 respondents per survey. FDA also projects a response time of 0.5 hours per response. These estimates are based on the maximum sample size per questionnaire that FDA may be able to obtain by working with healthcare professional organizations. The annual number of surveys was determined by the maximum past number of surveys per year FDA has conducted under this collection.

Respondents to this collection of information will be identified when additional surveillance data will address a potential public health hazard. For example, respondents could include facilities or professionals that have the most experience in the use of certain FDA-regulated products, foods, cosmetics, dietary supplements, animal food and feed, drugs, tobacco products, etc. Once FDA identifies the need for additional surveillance data to address a potential public health hazard, the appropriate respondents will be identified either through FDA's lists or through the appropriate professional organizations.

In the **Federal Register** of February 5, 2020 (85 FR 6559), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Numbers of respondents	Numbers of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA Rapid Response Survey	10,000	6	60,000	0.5 (30 minutes)	30,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: August 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–17928 Filed 8–14–20; 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