accommodate greater participation. FDA developed this draft guidance in part to respond to issues and questions raised in the discussion at that hearing and in many of the public comments received.

Although the hearing was not exclusively about cannabidiol (CBD), this compound was a key discussion topic. FDA and many stakeholders have concerns about marketed products that contain CBD, including concerns about potential contamination and inaccurate or misleading labeling. FDA would like to reiterate that EPIDIOLEX® (cannabidiol) is the sole FDA-approved [2] product derived from an extract of the cannabis plant.

Many sponsors initiating clinical research for drugs containing cannabis and cannabis-derived compounds may be unclear regarding, or unfamiliar with, applicable drug quality expectations. In general, drugs containing cannabis and cannabis-derived compounds are subject to the same authorities and requirements as drugs containing any other substance. Drugs intended for human use are evaluated by FDA's Center for Drug Evaluation and Research (CDER [3]) to ensure that drugs marketed in the United States are safe and effective for their intended uses and will be manufactured in a manner that ensures quality. CDER has published extensive regulations and guidance documents regarding the drug development and review process. In addition, FDA's website contains useful explanations regarding drug research and development. Finally, CDER's Small Business and Industry Assistance helps small pharmaceutical businesses and industry navigate the wealth of information that FDA offers, and assists in understanding the regulation of human drug products.

FDA's support of drug development extends to drugs containing cannabidiol and other compounds found in cannabis. One important element is encouraging drug developers to meet with FDA early in their development programs—ideally, before submitting an investigational new drug (IND) application. The pre-IND meeting is an opportunity to obtain FDA input on research plans and required content for an IND submission. The pre-IND meeting can be valuable in planning a drug development program, especially if sponsors' questions are not fully answered by guidances and other information provided by FDA. Early interactions with FDA staff through a pre-IND meeting can answer sponsors' questions related to a specific drug development program and provide information that will assist them in preparing complete IND applications. Efficient use of FDA resources can lead to more efficient drug development.

The FDA web page ''FDA and Cannabis: Research and Drug Approval Process'' (available at *https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process*) provides the basic roadmap for conducting clinical research at FDA using cannabis and cannabis-derived compounds. The resources on this page may be helpful to those interested in better understanding FDA processes for conducting clinical trials using cannabis and cannabis-derived compounds.

Calculating the amount of a substance in a botanical raw material by dry weight is a standard procedure. However, the calculation of dry weight for an extract or solid oral dosage form is less familiar to many stakeholders than the standard calculation for botanical raw materials. Therefore, the draft guidance recommends calculating delta-9 THC by dry weight in intermediates and drug products by removing the water content, including water contained in excipients. We invite comment from the public on this recommended approach. In addition, FDA invites public comment on the appropriate manufacturing controls over materials that cross under the 0.3 percent delta-9 THC by dry weight threshold during the production of a drug that contains cannabis or cannabis derived compounds.

This 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 ''Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research.'' 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

FDA tentatively concludes that this draft 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 draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR parts 312 and 314 for submission and approval of applications for investigational drugs and new drugs have been approved under OMB control numbers 0910–0014 and 0910–0001 respectively; and current Good Manufacturing Practices for Finished Pharmaceuticals as outlined in 21 CFR parts 210 and 211 have been approved under OMB control number 0910–0139.

III. Electronic Access

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

Dated: July 16, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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BILLING CODE 4164–01–P

[2] See Epidiolex drug approval package and labeling, available at *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210365Orig1s000TOC.cfm.*

[3] FDA's Center for Biologics Evaluation and Research (CBER) also has regulatory responsibilities with respect to the review of human drugs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of a Supplemental Award, Initiated by the Maternal and Child Health Bureau, to the University of Mississippi Medical Center for the Early Childhood Developmental Health System: Implementation in a High Need State Cooperative Agreement

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

ACTION: Notice of a Supplemental Award.

SUMMARY: HRSA announces the award of a supplement for $3,500,000 to the University of Mississippi Medical Center for the Early Childhood Developmental Health System: Implementation in a High Need State program. The supplement will add another year of funding to the current recipient, during the period of September 30, 2020–September 29, 2021, to continue a study focused on improving child health through a statewide system of early childhood developmental screenings and interventions.

FOR FURTHER INFORMATION CONTACT: Dina Lieser, Division of Home Visiting and Early Childhood Systems, HRSA, 26 Federal Plaza, Room 3337, New York,

NY 10278, Phone: (240) 463–7726 or Email: *dlieser@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Intended Recipient of Award: University of Mississippi Medical Center.

Amount of Award: $3,500,000.

Project Period: 09/30/2020–09/29/2021.

CFDA Number: 93.110.

Authority: Social Security Act, Title V, § 501(a)(2), (42 U.S.C. 701(a)(2)).

Justification: The Early Childhood Developmental Health System: Implementation in a High Need State program was first funded in September 2017. At that time, HRSA awarded $3,500,000 to the University of Mississippi Medical Center for a 3-year project period to conduct this program. After an extensive needs assessment of children ages 0–5 years and their families in Mississippi, progress has been made towards goals articulated in the Notice of Funding Opportunity: (1) Increasing the proportion of children receiving age appropriate developmental screening and (2) increasing the number of the state's early childhood providers who demonstrate improved practices around developmental health promotion.

The purpose of the non-competitive supplement from HRSA is to give the recipient the opportunity to maximize the efficiency, reach and impact of the program and leverage findings that will be valuable to other states. This extended year will allow the recipient to continue efforts to promote systemic change and support spread, scale, and sustainability of interventions and impact. The lessons learned and progress made in the first 3 years of the program will help to increase understanding of facilitators and barriers to implementation and will serve as a model for other states.

Grantee/organization name	Grant No.	State	FY 2019 authorized funding level	FY 2020 proposed funding level
University of Mississippi Medical Center	UK2MC31456	MS	$3,500,000	$3,500,000

Thomas J. Engels,

Administrator.

[FR Doc. 2020–15802 Filed 7–21–20; 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.

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, 2020, through June 30, 2020. 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