

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 FDA developed this draft guidance in part to respond to issues and questions raised in the discussion at that hearing and in many of the public comments received.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-approved² 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 (CDER³) 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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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,

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.

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](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