Administrative Orders Under Section 505G of the Federal Food, Drug, and Cosmetic Act.'' This draft guidance provides recommendations for industry and review staff on the formal dispute resolution and administrative hearings procedures for resolving scientific and/or medical disputes between CDER and requestors [1] and sponsors [2] of drugs that will be subject to a final order under section 505G of the FD&C Act (21 U.S.C. 355h).

Section 505G of the FD&C Act was added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136), which was enacted on March 27, 2020. After FDA issues a final order in accordance with section 505G(b)(2) of the FD&C Act, FDA must afford eligible requestors or sponsors the opportunity for formal dispute resolution (FDR) and hearings on disputes over the final order. This draft guidance describes the FDR procedures for eligible requestors or sponsors that wish to appeal a scientific and/or medical issue related to a final order. This draft guidance also outlines the procedures for an administrative hearing related to a final order. Finally, as required by section 505G(l)(4) of the FD&C Act, this draft guidance describes the procedures for consolidated proceedings for FDR and hearings to resolve the scientific and/or medical disputes.

In support of the CARES Act, FDA agreed to specific performance goals and procedures described in the document ''Over-the-Counter Monograph User Fee Program Performance Goals and Procedures—Fiscal Years 2018–2022,'' commonly referred to as the OMUFA commitment letter (the document can be accessed at *https://www.fda.gov/media/106407/download,* and the document with updated goal dates for fiscal years 2021–2025 can be accessed at *https://www.fda.gov/media/146283/download*). The OMUFA commitment letter specifies that FDA will revise the guidance for industry and review staff entitled ''Formal Dispute Resolution: Sponsor Appeals Above the Division Level'' (existing FDR guidance), available at *https://www.fda.gov/media/126910/download,* to include circumstances and procedures under which FDR may be used with respect to final orders under section 505G of the FD&C Act. In addition, consistent with the statutory requirement under 505G(l)(4), the OMUFA commitment letter explains that FDA will issue guidance on its views regarding best practices for consolidated proceedings for appeals.

For administrative efficiency, rather than amend the existing FDR guidance to include FDR procedures for final orders and issue a separate guidance for consolidated proceedings for appeals, FDA is issuing this single draft guidance. This draft guidance addresses the process for resolving scientific and/or medical disputes of final orders, including FDR, administrative hearings, and consolidated proceedings. FDA has incorporated recommendations from the existing FDR guidance as appropriate.

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 ''Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Federal Food, Drug, and Cosmetic Act.'' 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

Under section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 does not apply to collections of information made under section 505G of the FD&C Act. The information collections made in this guidance implement the provisions of the following subsections of 505G:

(1) Section 505G(l)(4), which requires FDA to issue guidance that specifies the consolidated proceedings for appeal and the procedures for such proceedings where appropriate;

(2) Section 505G(b)(2)(A)(iv)(III), which requires that FDA afford requesters of drugs that will be subject to final administrative orders the opportunity for formal dispute resolution up to the level of the Director of CDER;

(3) Section 505G(b)(3) and section 505G(b)(4)(E), which allow persons who participated in each stage of FDR with respect to a drug to request a hearing concerning a final administrative order with respect to such drug. Under Section 505G(b)(3)(C)(ii), a single hearing may be conducted if more than one request is submitted with respect to the same administrative order; and

(4) Section 505G(j), which requires that all submissions must be in electronic format.

Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) is not required for these collections of information.

In addition, this guidance does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information for OTC monograph products, OTC monograph order requests, and the OTC Monograph User Fee Program have been approved under OMB control number 0910–0340.

III. Electronic Access

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

Dated: June 16, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–13331 Filed 6–22–23; 8:45 am]

BILLING CODE 4164–01–P

[1] Requestor is defined in section 505G(q)(3) of the FD&C Act as any person or group of persons marketing, manufacturing, processing, or developing a drug.

[2] Sponsor is defined in section 505G(q)(2) of the FD&C Act as any person marketing, manufacturing, or processing a drug that is listed pursuant to section 510(j) of the FD&C Act and is or will be subject to an administrative order under section 505G of the FD&C Act.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1727]

Advisory Committee; Medical Imaging Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Medical Imaging Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Medical Imaging Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the May 18, 2025, expiration date.

DATES: Authority for the Medical Imaging Drugs Advisory Committee will expire on May 18, 2025, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, *MIDAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Medical Imaging Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 12 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of nuclear medicine, radiology, epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees, representatives, or Ex-Officio members. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/medical-imaging-drugs-advisory-committee/medical-imaging-drugs-advisory-committee-charter* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: June 16, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–13330 Filed 6–22–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Non-Federal Funds Reported by State/Jurisdiction Awardees on the Maternal, Infant, and Early Childhood Home Visiting Program for the Purposes of Meeting Maintenance of Effort Requirements (2019 and 2021)

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

ACTION: Notice.

SUMMARY: HRSA announces the publication of the amount of non-Federal funds each Maternal, Infant, and Early Childhood Home Visiting Program state/jurisdiction awardee has reported expending for fiscal years (FY) 2019 and 2021 for the purposes of meeting maintenance of effort requirements under this provision.

FOR FURTHER INFORMATION CONTACT: Nate Stritzinger, Policy Analyst, Division of Home Visiting and Early Childhood Systems, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, MD 20857; telephone: (301) 443–8590; email: *nstritzinger@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The MIECHV Program, authorized by section 511 of the Social Security Act, 42 U.S.C. 711, as amended by The Jackie Walorski Maternal and Child Home Visiting Reauthorization Act of 2022 (Section 6101 of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328)), is administered by HRSA in partnership with the Administration for Children and Families. Under section 511(f)(2) of the Social Security Act (42 U.S.C. 711(f)(2)), HRSA is required to publish the amount of non-federal funds each state/jurisdiction awardee has reported expending to satisfy the maintenance of effort (MOE) requirement for FY 2019 and 2021 no later than June 30, 2023. These amounts are listed in Table 1. For the Secretary to make an award to an eligible state or jurisdiction, that entity must meet the MOE requirement outlined in authorizing statute. To meet this requirement, beginning in FY 2023 the total amount of non-federal funds obligated by the eligible entity in the state or jurisdiction in the fiscal year for a MIECHV Program must not be less than the total amount of non-federal funds reported to have been expended by any eligible entity on evidence-based home visiting and home visiting initiatives for such a program in the state in FY 2019 or 2021, whichever is the lesser.

TABLE 1—MATERNAL, INFANT, AND EARLY CHILDHOOD HOME VISITING PROGRAM: NON-FEDERAL FUNDS REPORTED BY STATE/JURISDICTION TO SATISFY MOE REQUIREMENT FOR FY 2019 AND FY 2021

State/jurisdiction	Awardee name	FY 2019 MOE amt.	FY 2021 MOE amt.
Alaska	Alaska Department of Health and Social Services	$0.00	$0.00
Alabama	Alabama Department of Early Childhood Education	0.00	0.00
Arkansas	Arkansas Department of Health	0.00	0.00
American Samoa	American Samoa—Department of Health	0.00	0.00
Arizona	Arizona Department of Health Services	0.00	0.00
California	California Department of Public Health	1,879,834	11,948,600.00
Colorado	Colorado Department of Human Services	5,521,422.00	5,208,778.00
Connecticut	Connecticut Office of Early Childhood	10,217,642	10,278,822
District of Columbia	Government of the District of Columbia	707,808.76	635,825.88