with the order. Part XV requires that Vitagene provide the Commission additional information or compliance reports, as requested. Part XVI states that the proposed order will remain in effect for 20 years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order's terms.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2023–13329 Filed 6–22–23; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–2204]

Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Federal Food, Drug, and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 This draft guidance provides recommendations for industry and review staff on the formal dispute resolution and administrative hearings procedures for resolving scientific and/or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 the Center for Drug Evaluation and Research (CDER) and requestors and sponsors of drugs that will be subject to a final administrative order (final order) under section 505G of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the draft guidance by August 22, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2023–D–2204 for ''Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Federal Food, Drug, and Cosmetic Act.'' Received comments 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jung Lee, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5494, Silver Spring, MD 20993, 301–796–3599.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Formal Dispute Resolution and Administrative Hearings of Final

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.