FOR FURTHER INFORMATION CONTACT: Charlotte Conway, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6768, *charlotte.conway@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act) gives FDA the authority to regulate substances used in animal food. Section 201(s) of the FD&C Act (21 U.S.C. 321(s)) defines a food additive, in part, as any substance whose intended use results or may reasonably be expected to result, directly or indirectly, in it becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety . . . to be safe under the conditions of its intended use. Substances that are ''generally recognized as safe'' (GRAS) [1] for their intended uses in food are not food additives.

Section 409(b) of the FD&C Act (21 U.S.C. 348(b)) and FDA's implementing regulations at title 21 of the Code of Federal Regulations (21 CFR) part 571 describe the animal food additive petition process and the data and information that must be submitted to FDA as part of an animal food additive petition to support premarket approval. In general, to be legally marketed and used, a food additive must be approved, covered by an FDA regulation, and used as described in the FDA regulation. Otherwise, the food additive is considered unsafe under section 409(a)(2) of the FD&C Act, and the food additive and any food that bears or contains it is adulterated under section 402(a)(2)(C)(i) of the FD&C Act. Approved food additives for animal food use are found in 21 CFR parts 573 and 579.

FDA has affirmed certain substances as GRAS for their intended use in animal food and these are listed in 21 CFR parts 582 and 584. Importantly, these lists are not all-inclusive. FDA's Animal Food GRAS Notification Program allows individuals and firms to voluntarily notify FDA that they have concluded that an animal food substance is GRAS under the conditions of its intended use. FDA evaluates the notifier's supporting data and responds to the notifier with a letter stating whether FDA has questions about the notifier's conclusion. If FDA does not have questions, it issues a ''no questions'' letter. A ''no questions'' letter is not a legal determination by FDA that the use of a substance is GRAS. These notices are posted on FDA's website under ''Current Animal Food GRAS Notices Inventory,'' along with FDA's letter to the notifier regarding its evaluation of the notice.[2] FDA encourages any person who intends to market a food substance on the basis of a conclusion of GRAS status to submit a GRAS notice to FDA.

The Association of American Feed Control Officials (AAFCO) is an independent organization with voluntary membership of State and Federal regulatory officials in the United States, as well as officials from government agencies in other countries, that are responsible for the execution of laws and regulations in their jurisdictions pertaining to the production, labeling, distribution, use, or sale of animal food (including ingredients). FDA is a member of AAFCO and provides scientific and technical expertise to the organization.

Since 1920, AAFCO has maintained the AAFCO Official Publication, which contains, among other things, a comprehensive list of animal food ingredients, many of which include definitions established through the AAFCO ingredient definition request process. In 2007, FDA entered into a memorandum of understanding (MOU) with AAFCO that outlines how FDA would provide its scientific and technical expertise to AAFCO in reviewing requested ingredient definitions. This MOU has been renewed and revised several times. The current MOU 225–07–7001 expires on October 1, 2024, and will not be renewed. See *https://www.fda.gov/animal-veterinary/animal-food-feeds/fda-letter-stakeholders-acknowledgment-expiring-fda-aafco-mou.*

Elsewhere in this issue of the **Federal Register**, we are publishing a notice of availability for a draft guidance for industry #293, ''FDA Enforcement Policy for AAFCO-Defined Animal Feed Ingredients.'' This draft guidance, when finalized, will communicate FDA's current thinking on an enforcement policy regarding certain ingredients listed in chapter six of the 2024 AAFCO OP after the expiration of the Agency's MOU with AAFCO.

Elsewhere in this issue of the **Federal Register**, we also are publishing a notice of availability for a draft guidance on our new Animal Food Ingredient Consultation (AFIC) process to provide an additional way for firms developing animal food ingredients to consult with CVM following the expiration of the MOU with AAFCO while FDA evaluates the Food Additive Petition and GRAS Notification programs to determine if changes are needed to promote their efficiency.

II. Questions for Consideration

We seek input on the following questions regarding the oversight of animal food ingredients:

1. What do you perceive as barriers and/or benefits to pursuing a Food Additive Petition or GRAS Notification?
2. Are there changes that could make the Food Additive Petition and GRAS Notification programs more feasible, such as regulatory changes, changes to guidance, or changes to FDA policy or processes?
3. Is there information that is currently required to be submitted in a Food Additive Petition or GRAS Notification that you do not think is necessary for evaluating the ingredient?
4. Is there information that is not currently required to be submitted in a Food Additive Petition or GRAS Notification, but should be to better enable FDA's evaluation?
5. What review process for proposed animal food ingredients would best enable FDA to review their safety?
6. If you have submitted a request for an ingredient definition through the AAFCO ingredient definition process, what was your reason for doing so instead of filing a Food Additive Petition or submitting a GRAS Notification with FDA?

Dated: August 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17779 Filed 8–8–24; 8:45 am]

BILLING CODE 4164–01–P

[1] See 21 CFR part 570, subpart E.

[2] *https://www.fda.gov/food/generally-recognized-safe-gras/gras-notice-inventory.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3617]

Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Psychopharmacologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Clozapine Risk Evaluation and Mitigation Strategy

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Drug Safety and Risk Management Advisory Committee and the Psychopharmacologic Drugs Advisory Committee (the Committees). The general function of the Committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on November 19, 2024, from 8:30 a.m. to 4:30 p.m. Eastern Time.

ADDRESSES: The public may attend the meeting at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. The public will have the option to participate, and the advisory committee meeting will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2024–N–3617. The docket will close on November 18, 2024. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 18, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before November 4, 2024, will be provided to the Committees. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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–2024–N–3617 for ''Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Psychopharmacologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Clozapine Risk Evaluation and Mitigation Strategy (REMS).'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.'' FDA 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 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 the 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.

FOR FURTHER INFORMATION CONTACT: Joyce Frimpong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, email: *DSaRM@fda.hhs.gov,* 301–796–7973, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The Committees will discuss the reevaluation of the Clozapine Risk Evaluation and Mitigation Strategy (REMS) and possible changes to minimize burden on patients,

pharmacies, and prescribers while maintaining safe use of clozapine.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at the location of the advisory committee meeting and at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting presentations will also be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. The online presentation of materials will include slide presentations with audio and video components in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committees. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before November 4, 2024, will be provided to the Committees. Oral presentations from the public will be scheduled between approximately 1:20 p.m. and 2:20 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, whether they would like to present online or in-person, and an indication of the approximate time requested to make their presentation on or before October 25, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. Similarly, room for interested persons to participate in-person may be limited. If the number of registrants requesting to speak in-person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the advisory committee meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in-person. The contact person will notify interested persons regarding their request to speak by October 28, 2024. Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Joyce Frimpong (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform in conjunction with the physical meeting room (see location). This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: August 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17752 Filed 8–8–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–2827]

Optimizing the Dosage of Human Prescription Drugs and Biological Products for the Treatment of Oncologic Diseases; 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 final guidance for industry entitled ''Optimizing the Dosage of Human Prescription Drugs and Biological Products for the Treatment of Oncologic Diseases.'' This guidance is intended to assist sponsors in identifying an optimized dosage(s) for human prescription drugs or biological products for the treatment of oncologic diseases during clinical development prior to submitting an application for approval for a new indication and usage. This guidance does not address selection of the starting dosage for first-in-human trials. In addition, this guidance does not address dosage optimization for radiopharmaceuticals, cellular and gene therapy products, oncolytics, microbiota, or cancer vaccines, nor does it specifically address pediatric drug development. However, some of the principles outlined may be applicable to these therapeutic modalities or to dosage optimization for pediatric patients. This guidance finalizes the draft guidance of the same title ''Optimizing the Dosage of Human Prescription Drugs and Biological Products for the Treatment of Oncologic Diseases'' issued on January 23, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on August 9, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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