Medicine (HFV–147), Food and Drug Administration, 7500 Standish Place, Rockville MD 20855, 240–402–0651, *Heather.Longstaff@fda.hhs.*

SUPPLEMENTARY INFORMATION:

I. Background

The FDA is announcing the availability of a draft GFI #292 entitled ''Chemistry, Manufacturing, and Controls Considerations for Type A Medicated Articles.'' This draft guidance provides recommendations to sponsors submitting CMC information for Type A medicated articles. Type A medicated articles contain new animal drugs and provide for administration of these drugs in animal feed. Type A medicated articles are intended solely for use in the manufacture of another Type A medicated article or in the manufacture of a Type B or Type C medicated feed. Because Type A medicated articles are not directly administered to the animal, there are some issues specific to Type A medicated articles that do not apply to other new animal drug dosage forms. These unique considerations are highlighted in this guidance under the relevant Common Technical Document—Quality section headings.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Chemistry, Manufacturing, and Controls Considerations for Type A Medicated Articles.'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 514 have been approved under OMB control numbers 0910–0032; the collections of information in 21 CFR 511.1 have been approved under OMB control number 0910–0117; and the collections of information in sections 512(b) and 512(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b) and 360b(n)) have been approved under OMB control number 0910–0669.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or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

Dated: June 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13796 Filed 6–21–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2561]

Best Practices for Meeting Management; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Best Practices for Meeting Management.'' This workshop is being conducted to fulfill a commitment to hold a public meeting to discuss best practices for meeting management in the seventh authorization of the Prescription Drug User Fee Act (PDUFA VII). The purpose of the public workshop is to discuss issues related to submission of meeting requests, efficient time management, finalizing meeting agenda, development and submission of meeting background packages, and lessons learned from the Coronavirus Disease 2019 (COVID–19) pandemic including the use of virtual meeting platforms. The public workshop will also discuss and share experience and metrics related to specific PDUFA meeting activities associated with the Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) meetings in fiscal years (FYs) 2021 through 2023. This will include Type D and Initial Targeted Engagement for Regulatory Advice on CBER/CDER Products (INTERACT) meetings, which began with PDUFA VII in FY 2023. Learnings from the public meeting could inform FDA's internal process improvement efforts and, as appropriate, be reflected in an update to the ''Best Practices for Communication Between IND [Investigational New Drug Application] Sponsors and FDA During Drug Development'' guidance.

DATES: The public workshop will be held in person and virtually on July 22, 2024, from 9 a.m. to 2 p.m., Eastern Time. Either electronic or written comments on this public workshop must be submitted by August 22, 2024. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held in person at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room, Silver Spring, MD 20993–0002 and virtually using the Zoom platform. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.*

You may submit comments as follows. 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 August 22, 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.

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–2561 for ''Best Practices for Meeting Management; Public Workshop; Request for Comments.'' 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.'' 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.

FOR FURTHER INFORMATION CONTACT: Danielle Villata, Center for Drug Evaluation and Research, Food and Drug Administration, 301–796–3800, *Danielle.Villata@fda.hhs.gov* or Sonday Kelly, Center for Biologics Evaluation and Research Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–8410, *Sonday.Kelly@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Timely and effective interactive communications with sponsors during drug development is a core Agency activity to help achieve the Agency's mission to facilitate the conduct of efficient and effective drug development programs, which can enhance public health by making new, safe, and effective drugs available to the American public. Through PDUFA, FDA has established numerous meeting opportunities with sponsors such as Type A, B, and C meetings in addition to communications that take place during the review of certain marketing applications such as mid-cycle telecons and late-cycle meetings. PDUFA VII added two new meeting types, the INTERACT and Type D meetings.

Due to the significant volume of FDA and sponsor interactions over the years, the addition of multiple new meeting/communication types, and format changes to interactions (*e.g.,* extended use of virtual meetings) due to the COVID–19 pandemic, updating FDA's and Industry's standards for meeting management best practices has become more important.

Best practices for meeting management are the responsibility of Industry and FDA and efforts from both are needed to continue advancement and improvement of these communications. To that end, FDA hired a contractor to gather and analyze FDA meeting metrics and feedback for discussion at a public workshop to identify best practices for effective FDA-sponsor meeting management. This public workshop is intended to fulfill a commitment FDA agreed to under the FDA User Fee Reauthorization Act of 2022, in accordance with the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027 letter (PDUFA VII letter), which is available at *https://www.fda.gov/media/151712/download.* Specifically, section I.K.1 of the PDUFA VII letter outlines efforts to enhance communication between FDA and sponsors during drug development, and the Agency's intent to hold a public workshop to discuss best practices for meeting management by July 30, 2024.

II. Public Workshop Topics for Discussion

The public workshop will facilitate discussion on issues related to submission of meeting requests, efficient time management, finalizing meeting agenda, development and submission of meeting background packages to enable effective communication and lessons learned from the COVID–19 pandemic including virtual meeting platforms. Based on an analysis of meeting management practices prepared by the contractor, this public workshop will provide a forum to discuss and share experiences related to specific PDUFA meeting activities associated with CBER and CDER meetings in FYs 2021 through 2023. This will include Type D and INTERACT meetings, which began with PDUFA VII in FY 2023. FDA will discuss the number of meeting requests granted and denied for INTERACT meetings and provide a summary of rationales for denied meeting requests. Reported metrics will include the number of requests granted and denied for in-person pre-IND, Type C, Type D, and INTERACT meetings.

Workshop updates, agenda, and background materials (if any) will be made available at *https://www.fda.gov/drugs/news-events-human-drugs/public-workshop-best-practices-meeting-management-under-pdufa-vii-07222024* prior to the workshop.

III. Participating in the Public Workshop

Registration: To register for this hybrid public workshop, please visit the following website: *https://fda.zoomgov.com/webinar/register/WN_2im_5zChQ8WvhX_kfS3CdQ.* Please provide complete contact information for each attendee, including attendance format (in-person or virtual), name, title, affiliation, and email. You will be asked to indicate in your registration if you plan to attend in person or via the Zoom webinar.

Registration for in-person attendance will close on July 8, 2024, 11:59 p.m. Eastern Time. Registration for the webinar will remain open until the day

of the workshop. Registration is free and in-person attendance is based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. Onsite registration on the day of the workshop will be based on space availability.

If you need special accommodations due to a disability, please contact Danielle Villata (see **FOR FURTHER INFORMATION CONTACT**) no later than July 8, 2024, 11:59 p.m. Eastern Time.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session. You must register online to present comments during the public workshop. All requests to make oral presentations must be received by the close of registration on July 8, 2024, 11:59 p.m. Eastern Time. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by July 15, 2024. If selected for presentation, any presentation materials must be emailed to Danielle Villata (see **FOR FURTHER INFORMATION CONTACT**) no later than July 18, 2024, 11:59 p.m. Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming of the Public Workshop: This public workshop will also be available via Zoom webinar to registered attendees. To view the Zoom webinar of this public workshop, please register at *https://fda.zoomgov.com/webinar/register/WN_2im_5zChQ8WvhX_kfS3CdQ*. For more information about Zoom, please visit *https://support.zoom.us/hc/en-us/articles/206175806-Frequently-asked-questions.*

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may also be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: June 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13776 Filed 6–21–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 062

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 062'' (Recognition List Number: 062), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written comments on the notice at any time. These modifications to the list of recognized standards are applicable June 24, 2024.

ADDRESSES: You may submit comments on the current list of FDA Recognized Consensus Standards 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–2004–N–0451 for ''Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 062.'' 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. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 062.

- 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