MD 20750, 301–796–5276, *Monica.Ellerbe@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The meeting will include presentations from FDA on: (1) The 5-year plan for the Prescription Drug User Fee Act (PDUFA) VI, Biosimilar User Fee Act (BsUFA) II, and Generic Drug User Fee Amendments (GDUFA) II; (2) the Agency's progress in implementing resource capacity planning and modernized time reporting; and (3) the Agency's progress in addressing the findings from the independent third-party evaluation of the resource management associated with PDUFA, BsUFA, and GDUFA that concluded and was published in fiscal year (FY) 2019. This meeting is intended to satisfy FDA's commitment to host an annual public meeting in the third quarter of each fiscal year beginning in FY 2019 and can be found in the Commitment letters listed below (II.B.3 of PDUFA VI (p. 38), IV.B.3 of BsUFA II (p. 28), and VI.B.4 of GDUFA II (p.22)).

This public meeting is intended to meet performance commitments included in PDUFA VI, BsUFA II, and GDUFA II. These user fee programs were reauthorized as part of the FDA Reauthorization Act of 2017 (FDARA) signed by the President on August 18, 2017. The complete set of performance goals for each program are available at:

- *PDUFA VI program: https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf*
- *BsUFA II program: https://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/ucm521121.pdf*
- *GDUFA II program: https://www.fda.gov/downloads/forindustry/userfees/genericdruguserfees/ucm525234.pdf*

Each of these user fee programs includes a set of commitments related to financial management. These include commitments to publish a 5-year financial plan that should be updated annually, develop resource capacity planning capability and to modernize time reporting practices, and have a third-party evaluation of resource management practices for these user fee programs. In addition, each user fee program includes a commitment to host a public meeting in the third quarter of each fiscal year, beginning in FY 2019, to discuss specific topics.

II. Topics for Discussion at the Public Meeting

This meeting will provide FDA the opportunity to update interested public stakeholders on topics related to the financial management of PDUFA VI, BsUFA II, and GDUFA II. FDA will present the 5-year financial plans for each of these programs and update participants on the progress towards implementing resource capacity planning and modernizing its time reporting approach. In addition, FDA will provide an update on the Agency's progress in addressing the findings from the independent third-party evaluation of the resource management associated with PDUFA, BsUFA, and GDUFA that concluded and was published in FY 2019. To view the evaluation assessment report, please visit here: *https://www.fda.gov/media/127605/download.*

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: *https://www.surveymonkey.com/r/FDA_2021_User_Fees_Public_Meeting_Registration.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Persons interested in attending this public meeting must register by June 15, 2021, at 11:59 p.m. Eastern Time.

If you need special accommodations due to a disability, please contact Monica Ellerbe no later than June 15, 2021, 11:59 p.m. Eastern Time.

Streaming Webcast of the Public Meeting: The webcast for this public meeting is *https://fda1.webex.com/fda1/onstage/g.php?MTID=e1c96ecf18f93ce5f76a24967fa89af65;* Password: FDApm2021.

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

Dated: May 14, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10566 Filed 5–18–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0351]

Chemotherapy-Induced Nausea and Vomiting: Developing Drugs for Prevention; 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 ''Chemotherapy-Induced Nausea and Vomiting: Developing Drugs for Prevention.'' This guidance addresses FDA's current thinking regarding clinical trials for drugs for the prevention of chemotherapy-induced nausea and vomiting (CINV) in adults, including recommendations for trial population, trial design, efficacy considerations, and clinical outcome assessments. This guidance details a recent change in our recommendations regarding the necessary evidence and recommended endpoint assessments needed to support a determination of efficacy for the indication of the prevention of CINV. Previously, drug development programs seeking an indication for the prevention of CINV typically selected a primary efficacy endpoint of complete response, defined as no vomiting and no use of rescue antiemetic medication, with additional direct evaluation of nausea frequency and severity positioned as exploratory assessments. To promote consistency and interpretability in the assessment of nausea both within and across development programs, FDA now recommends sponsors analyze a primary endpoint of complete response (*i.e.,* a binary endpoint defined as no vomiting and no use of rescue antiemetic medication) and a secondary endpoint of the absence of nausea (*i.e.,* a binary endpoint defined as no reported nausea and no use of rescue antiemetic medication) by evaluating the difference in the proportions of responders across treatment arms to establish efficacy for the prevention of CINV.

DATES: Submit either electronic or written comments on the draft guidance by July 19, 2021 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–2021–D–0351 for ''Chemotherapy-Induced Nausea and Vomiting: Developing Drugs for Prevention.'' 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: Mary Chung, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5350, Silver Spring, MD 20993–002, (301) 796–0260.

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Chemotherapy-Induced Nausea and Vomiting: Developing Drugs for Prevention.'' This draft guidance addresses FDA's current thinking regarding clinical trials for the prevention of CINV in adults, including recommendations for trial population, trial design, efficacy considerations, and clinical outcome assessments.

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 ''Chemotherapy-Induced Nausea and Vomiting: Developing Drugs for Prevention.'' 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. 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 for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in support of submission and review of data for applications for FDA review and approval of new drugs or therapeutic biologics under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) have been approved under OMB control numbers 0910–0014, 0910–0001, and 0910–0338.

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: May 14, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10573 Filed 5–18–21; 8:45 am]

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