of, or even eliminate the need for, in vivo studies to establish BE.

While QMM approaches that generate MIE provide significant value to the development, review, and approval of high-quality generic drugs, these frameworks are evolving amidst challenges and complications facing industry that are incidental to the growing use of new and complex modeling technologies. For example, the data and information needed to verify and validate a model may not be available to the general public (*e.g.,* proprietary), or if publicly available, insufficient, and generating original data for model verification and validation (V&V) can be a time-consuming and costly investment. At the same time, certain M&S approaches may provide an opportunity for certain models, once they are supported by sufficient V&V, to be viewed as shareable across different products and formulations and utilized by multiple ANDA applicants for the same context of use. For purposes of this notice, an ''MMF'' or ''MMF submission'' refers to a set of information and data on an in silico quantitative model or modeling platform supported by sufficient V&V. MMFs can be established to support MIE in a broad range of quantitative models, including, but not limited to, PBPK, CFD, PPK, and mechanistic in vitro in vivo correlation models. There are different types of MMFs, including, but not limited to, drug product-specific models, a verified and validated in silico framework for products following the same route of administration, and a recognized modeling methodology or framework for a particular context of use (Ref. 1).

FDA recognizes the evolving role MIE plays in generic drug development and other regulatory applications, as well as industry's corollary desire for an improved framework for in silico model-sharing, model acceptance, and related communication with and submission to FDA. Use of the Type V DMF to efficiently leverage MMFs within the scope of successful MIE approaches may help advance generic drug development and facilitate the ANDA review and approval processes.

A DMF is a voluntary submission that may be used to provide confidential detailed information to the Agency (Ref. 2). A DMF is submitted solely at the discretion of the DMF holder. There are several types of DMFs; a Type V is used for ''FDA-accepted reference information.'' (§ 314.420(a)(5) (21 CFR 314.420(a)(5))). The use of a DMF is not a requirement for the submission of MMFs to the Agency; however, the holder of a Type V DMF can authorize one or more ANDA applicants to incorporate by reference information and data contained in the DMF without having to disclose that information and data to the applicant(s). When authorized by the DMF holder, ANDA applicants can use information and data contained in the DMF to support, but not substitute for, their ANDA submissions. A DMF is neither approved nor disapproved. Its technical content (in this case, the MMF) is typically reviewed by FDA only in connection with the review of a premarket application (Ref. 2 at 6). A Type V DMF, including a Type V DMF for MMF submissions to support an ANDA, may be submitted on an ongoing basis.

Prospective DMF holders who are interested in using a Type V DMF, including a Type V DMF for MMF submissions to support ANDAs, must first email a letter of intent to the DMF staff (see Ref. 2 at 16 (citing § 314.420(a)(5))). The draft guidance for industry ''Drug Master Files'' provides detailed information about preparing and submitting DMFs and FDA's DMF review process, including that an emailed letter of intent should be sent to (*dmfquestion@fda.hhs.gov*) and include a clearly stated subject field and other necessary information (Ref. 2 at 16). For example, applicants that have submitted a Type V DMF for MMF submissions to support ANDAs have submitted the letter of intent with a subject field, such as ''Letter of Intent to Submit Type V DMF for MMF Submission to Support ANDAs''. For more information on submitting Type V DMFs, see FDA's DMF web page and the FDA Guidance for Industry ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions using the eCTD Specifications'' (Ref. 3).[2]

II. Request for Comments

FDA is opening a docket to solicit feedback from the public on the use of a Type V DMF for MMF submissions to support ANDAs. FDA welcomes any relevant information that interested parties and other members of the public wish to share. At the close of the comment period, the Agency will collect this feedback for consideration.

III. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. Although FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Fang, L., Y. Gong, A.C. Hooker, et al., 2024, ''The Role of Model Master Files for Sharing, Acceptance, and Communication with FDA,'' *The AAPS Journal,* 26(2):28–35 available at 10.1208/s12248–024–00897–8.

* 2. FDA Draft Guidance for Industry ''Drug Master Files,'' October 2019: *https://www.fda.gov/media/131861/download.*

* 3. FDA Guidance for Industry ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions using the eCTD Specifications,'' September 2024, Rev. 8: *https://www.fda.gov/media/135373/download.*

Dated: January 14, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01182 Filed 1–16–25; 8:45 am]

BILLING CODE 4164–01–P

[2] See also, FDA's DMF web page, available at *https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–5663]

Prevention and Treatment of Chemotherapy-Induced Peripheral Neuropathy: Developing Drug and Biological Products in Oncology; 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 ''Prevention and Treatment of Chemotherapy-Induced Peripheral Neuropathy: Developing Drug and Biological Products in Oncology.'' Chemotherapy-induced peripheral neuropathy (CIPN), a painful, disabling, and potentially irreversible condition commonly affecting patients receiving neurotoxic chemotherapies, could diminish survival by potentially increasing chemotherapy treatment interruptions, dose reductions, and discontinuations. This guidance

provides recommendations to sponsors for the clinical development of drug and biological products intended for the prevention and treatment of CIPN in oncology patient populations.

DATES: Submit either electronic or written comments on the draft guidance by March 18, 2025 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–2024–D–5663 for ''Prevention and Treatment of Chemotherapy-Induced Peripheral Neuropathy: Developing Drug and Biological Products in Oncology.'' 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 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Mirat Shah, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2135, Silver Spring, MD 20993, 301–796–8547; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Prevention and Treatment of Chemotherapy-Induced Peripheral Neuropathy: Developing Drug and Biological Products in Oncology.'' CIPN is a painful, disabling, and potentially irreversible condition commonly affecting patients receiving neurotoxic chemotherapies. CIPN could lead to chemotherapy treatment interruptions, dose reductions, and discontinuations. In addition, there is a concern that CIPN-mitigating drugs may decrease the efficacy of cancer treatment or possibly promote tumor growth. Thus, CIPN can negatively affect overall cancer treatment outcome and survival. This guidance provides recommendations to sponsors for the clinical development of drug and biological products intended for the prevention and treatment of CIPN in oncology patient populations. The recommendations include trial population, design, and selection of appropriate oncology-specific endpoints.

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 ''Prevention and Treatment of Chemotherapy-Induced Peripheral Neuropathy: Developing Drug and Biological Products in Oncology.'' 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 related to the protection of human subjects under 21 CFR part 50 have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: January 10, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01197 Filed 1–16–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3112]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarketing Adverse Experience Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by February 18, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0230. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Postmarketing Adverse Experience Reporting

OMB Control Number 0910–0230—Revision

This information collection helps support provisions found in sections 201, 502, 505, 701, and 760 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321, 352, 355, 371, and 379aa) governing adverse experience reporting (AER) and associated recordkeeping for FDA-regulated drug products. FDA has issued applicable regulations in part 4 and §§ 310.305, 314.80, 314.81, 314.98, and 329.100 (21 CFR part 4 and 21 CFR 310.305, 314.80, 314.81, 314.98, and 329.100) that implement the statutory requirements, identify specific content and format elements, and establish reporting and retention schedules for the required information. Postmarketing safety data collection and adverse event reporting are critical elements of FDA's monitoring of drugs. For more information, please visit *https://www.fda.gov/drugs/surveillance/postmarketing-adverse-event-reporting-compliance-program.*

Respondents to the information collection are manufacturers, packers, distributors, and applicants of FDA-regulated drug and biologic products marketed with or without an FDA-approved application, including over-the-counter (OTC) drug products marketed without an approved application; OTC drug products marketed under the OTC Drug Monograph Review process (whether subject to a final monograph or not); and drug products marketed outside the monograph system. All reports and followup reports must be submitted to FDA in electronic format, although waivers of the electronic requirements are available for good cause.

Adverse experience reporting for products associated with drug marketing applications are governed by regulations in §§ 314.80, 314.81, and 314.98. The regulations identify required reporting content and format elements, as well as establish followup reporting requirements and mandatory reporting schedules. The regulations also establish associated recordkeeping and require that written procedures be developed for the surveillance, receipt, evaluation, and reporting of postmarketing adverse experiences to FDA. The regulations require reporting in an electronic format that FDA can process, although temporary waivers may be granted on a limited basis for good cause. A final guidance for industry entitled ''Providing Submissions in Electronic Format—Postmarketing Safety Reports'' (April 2022) is available for general information pertaining to electronic submission of postmarketing safety reports for certain human drugs, biological products, and combination products. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-submissions-electronic-format-postmarketing-safety-reports.*

We have established and maintain the FDA Adverse Event Reporting System (FAERS) at *https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions.* Information may be submitted via FDA's Electronic Submissions Gateway or utilizing the ''Safety Reporting Portal,'' developed by FDA and the National Institutes of Health to streamline reporting and review of adverse events.

The primary purpose of FDA's adverse drug experience reporting system is to enable identification of signals for potentially serious safety problems with marketed drugs. Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the larger and more diverse patient populations exposed to the marketed product provide the opportunity to collect information on rare, latent, and long-term effects. Signals are obtained from a variety of sources, including reports from patients, treating physicians, foreign regulatory agencies, clinical investigators, and literature. Information derived from the adverse drug experience reporting system contributes directly to increased public