adequate time for interested persons to submit comments without significantly delaying guidance on these important issues.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Chemical Analysis for Biocompatibility Assessment of Medical Devices.'' 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. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Chemical Analysis for Biocompatibility Assessment of Medical Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00020037 and complete title to identify the guidance you are requesting.

Dated: October 17, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–24447 Filed 10–21–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–3903]

Drug Interaction Information in Human Prescription Drug and Biological Product Labeling—Content and Format; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Drug Interaction Information in Human Prescription Drug and Biological Product Labeling.'' The draft guidance is intended to assist applicants in developing the DRUG INTERACTIONS section of labeling as described in FDA regulations for the content and format of labeling for human prescription drug and biological products. The purpose of the draft guidance is to provide recommendations on what information to include in, and how to present and organize the information within, the DRUG INTERACTIONS section of labeling for human prescription drug and biological products to enhance communication of clinically significant drug interactions and facilitate the safe and effective use of prescription drugs by healthcare practitioners.

DATES: Submit either electronic or written comments on the draft guidance by January 21, 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–3903 for ''Drug Interaction Information in Human Prescription Drug and Biological Product Labeling; Draft Guidance for Industry.'' 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 this 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 the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Joseph Grillo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–0591; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Drug Interactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' The draft guidance is intended to assist applicants in developing the DRUG INTERACTIONS section of the Prescribing Information labeling as described in FDA regulations for the content and format of labeling for human prescription drug and biological products.[1]

Prescription drug labeling must contain a summary of the essential information necessary for safe and effective use of the drug and is a primary tool for FDA to communicate drug interaction information to healthcare practitioners. Effective communication of drug interaction information informs the optimal use of the drug and the healthcare practitioner's clinical decision-making (*e.g.,* prescribing decisions or management instructions).

The purpose of this guidance is to provide recommendations on what information to include in, and how to present and organize the information within, the DRUG INTERACTIONS section of prescription drug labeling to enhance communication of clinically significant drug interactions and facilitate the safe and effective use of prescription drugs by healthcare practitioners. This guidance also provides illustrative examples of the content and format of drug interaction information in prescription drug labeling.

In addition, the guidance includes an FDA website (*https://www.fda.gov/CYPandTransporterInteractingDrugs*) as one resource that health care practitioners can use to view examples of clinical substrates, inhibitors, and inducers of Cytochrome P–450 (CYP) enzymes and substrates and inhibitors of transporters. FDA is seeking input regarding the utility of this website as a resource that health care practitioners can reference to find examples of clinical substrates, inhibitors, and inducers of CYP enzymes and substrates and inhibitors of transporters. FDA is also seeking input on ways to describe drug interactions in labeling, specifically when drugs have numerous, clinically relevant drug interactions (*e.g.,* azole antimycotics) that require listing many interactions. In addition, FDA is seeking input on ways to describe complex drug-interaction scenarios, including but not limited to:

- Concurrent inhibition of an enzyme and a transporter by a drug;
- Concurrent inhibition and induction of a drug's metabolic pathway by one or more enzymes;
- Increased inhibition of drug elimination by use of inhibitors of more than one enzyme that metabolizes the drug;
- Inhibition of an enzyme other than the genetic polymorphic enzyme in poor metabolizers taking a substrate metabolized by both enzymes;
- Effect of enzyme/transporter inhibitors in subjects with organ impairment; and
- Two drugs acting as both precipitant and object of a drug interaction.

The draft guidance, when finalized, will represent the current thinking of FDA on ''Drug Interaction Information in Human Prescription Drug and Biological Product Labeling.'' 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 parts 314 and 601 are approved under OMB control numbers 0910–0001 and 0910–0338, respectively. The collections of information in 21 CFR parts 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

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

Dated: October 16, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–24442 Filed 10–21–24; 8:45 am]

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[1] 21 CFR 201.56(a) and (d) and 201.57(c)(8). This guidance applies to drugs, including biological products that are regulated as drugs. For the purpose of this guidance, ''drug product'' or ''drug'' will be used to refer to human prescription drug and biological products that are regulated as drugs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Request for Public Comments on Draft Recommendations for the HRSA-Supported Women's Preventive Services Guidelines Relating to Screening and Counseling for Intimate Partner and Domestic Violence, Breast Cancer Screening for Women at Average Risk, and Patient Navigation for Breast and Cervical Cancer Screening

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.