Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6485, Silver Spring, MD 20993, 301–796–0855; or Stephen Ripley, 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FDA is announcing the availability of a draft guidance for industry entitled ''Immunogenicity Information in Human Prescription Therapeutic Protein and Select Drug Product Labeling—Content and Format.''

Evaluation of a therapeutic protein product's and certain select drug products' immunogenicity (*e.g.,* risk of developing anti-drug antibodies, including neutralizing antibodies) and its potential clinical impact generally plays an important role in the assessment of the product's safety and effectiveness for each proposed indication. Because some, but not all, anti-drug antibodies have been associated with safety concerns or loss of effectiveness, FDA believes that presenting immunogenicity information in a consistent manner would enable health care practitioners to more easily differentiate products associated with anti-drug antibodies having clinical effect(s) from products with anti-drug antibodies that do not have a clinically meaningful effect on pharmacokinetics, pharmacodynamics, safety, or effectiveness.

This draft guidance recommends the use of a dedicated Immunogenicity subsection (subsection 12.6) under the CLINICAL PHARMACOLOGY section. Information and statements to include in this subsection (*e.g.,* data on anti-drug antibody incidence, clinical pharmacologic effects of anti-drug antibodies) are described in the draft guidance, along with recommended content to include in other sections of the labeling (*e.g.,* summary of anti-drug antibody-associated effects on safety and/or effectiveness in the WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and/or CLINICAL STUDIES sections, as applicable). The labeling recommendations are based on: (1) Adequacy of the methodology for detection of anti-drug antibodies, (2) sufficiency of available data to draw clinical conclusions, and (3) whether the anti-drug antibodies have clinically significant effect(s). In addition to recommendations on presentation of known immunogenicity information, this draft guidance also provides recommendations for consistently stating when such information is unknown, if appropriate. The draft guidance also provides procedural information, including recommendations for updating immunogenicity information in the Prescribing Information of applicable approved products.

When finalized, this guidance will supersede the immunogenicity labeling-specific recommendations from the guidance for industry entitled ''Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products—Content and Format'' (available at *https://www.fda.gov/media/74346/download*). When finalized, this guidance will also supersede the recommendations in section IV.C.3., ADVERSE REACTIONS, Immunogenicity, of the guidance for industry entitled ''Labeling for Biosimilar Products'' (available at *https://www.fda.gov/media/96894/download*), including the statement ''Immunogenicity information for therapeutic protein products is usually placed in a subsection in the ADVERSE REACTIONS section entitled Immunogenicity'' and statements recommended for inclusion as the first paragraph in the ADVERSE REACTIONS subsection that precedes the immunogenicity data. 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.

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 ''Immunogenicity Information in Human Prescription Therapeutic Protein and Select Drug Product Labeling—Content and Format.'' 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 new 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 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 600 have been approved under OMB control number 0910–0308. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572. The collections of information related to pharmacology data have been approved under OMB control number 0910–0014. The collections of information submitting biologics license applications under section 351(k) of the Public Health Service Act have been approved under OMB control number 0910–0719.

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

Dated: January 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02348 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2398]

Population Pharmacokinetics; 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 ''Population Pharmacokinetics.'' This guidance assists sponsors in the application of population pharmacokinetics (population PK) during the drug development process to inform drug use and includes FDA's current thinking on the data and model requirements for population PK analyses submitted as part of new drug applications (NDAs), biologic license applications (BLAs), and abbreviated new drug applications (ANDAs). This guidance also provides expectations regarding the format and content of the population PK report, as well as any

labeling recommendations resulting from such analyses. This guidance finalizes the draft guidance of the same title issued on July 12, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on February 4, 2022.

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 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–2019–D–2398 for ''Population Pharmacokinetics.'' 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 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 that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Hao Zhu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3132, Silver Spring, MD 20993, 301–796–2772; or Stephen Ripley, 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 final guidance for industry entitled ''Population Pharmacokinetics.'' Population PK analyses can quantify the impact of intrinsic and extrinsic patient factors on the exposure of a drug. In conjunction with supporting exposure-response data, population PK data can be used to identify patient factors that result in a clinically significant change in drug exposure and inform the proper use of drugs. Since FDA announced the publication of the original population PK guidance in 1999, the number of applications relevant for population PK analysis has increased, and the sophistication and reliability of population PK analysis methods have improved.

This guidance finalizes the draft guidance entitled ''Population Pharmacokinetics'' issued on July 12, 2019 (84 FR 33267). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include greater detail on the use of population PK modeling for biologics, handling of time-varying covariates, additional methods and terminology typically used for population PK analyses, and updates to format and content for submitting population PK reports. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Population Pharmacokinetics.'' 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

This guidance contains no new collection 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.

However, this guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001. The collections of information in 21 CFR parts 600 and 601 have been approved under OMB control number 0910–0338. The collections of information in 21 CFR 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 guidance at either *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.regulations.gov.*

Dated: January 31, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02355 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1636]

Assessment of Pressor Effects of Drugs; Revised 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 revised draft guidance for industry entitled ''Assessment of Pressor Effects of Drugs.'' This draft guidance is intended to advise sponsors on the premarketing assessment of a drug's effect on blood pressure. Elevated blood pressure is known to increase the risk of stroke, heart attack, and death. The effect of a drug on blood pressure is, therefore, an important consideration in risk assessment and product labeling. This draft guidance revises the draft guidance for industry ''Assessment of Pressor Effects of Drugs'' issued on May 31, 2018.

DATES: Submit either electronic or written comments on the draft guidance by April 5, 2022 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–2018–D–1636 for ''Assessment of Pressor Effects of Drugs.'' 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. 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: Devi Kozeli, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4183, Silver Spring, MD 20903, 301–796–2240.

SUPPLEMENTARY INFORMATION: