remind tribes that they can request a waiver if (1) a delay or disruption to program services is caused by circumstances beyond the agency's control, or, (2) if an agency is unable to administer the program within the 15 percent limitation and if the agency can demonstrate efforts to reduce its development and administrative costs (1303.5 (b)(1) of HSPPS). If at any time within the grant funding cycle, a tribe estimates development and administration costs will exceed 15 percent of total approved costs, they must submit a waiver request to the responsible HHS official that explains why costs exceed the limit, that indicates the time period the waiver will cover, and that describes what the grantee will do to reduce its development and administrative costs to comply with the 15 percent limit after the waiver period (1303.5 (b)(2) of HSPPS).

In accordance with Section 640(b) of the Act, federal financial assistance to a grantee will not exceed 80 percent of the approved total program costs. A grantee must contribute 20 percent as non-federal match each budget period. OHS also understands that some tribes are requesting to remove the non-federal share match requirement. While OHS does not have the authority to institute automatic waivers for the non-federal share requirement for tribes, OHS reminds tribes that if an AI/AN program has been actively seeking non-federal match but is struggling to meet its requirement, it can apply to its regional office for a waiver. The following circumstances covered in the Head Start Act are considered when approving waivers:

- Lack of community resources that prevent a Head Start or Early Head Start program from providing all or a portion of the required match
- Impact of the cost the program may incur as it starts a new program in its initial years of operation
- Impact of an unanticipated increase in costs the program may incur
- Impact of a major disaster in a community that prevents the program from meeting its match
- Impact on the community that would result if the Head Start or Early Head Start program ceased to operate

The responsible HHS official may approve a waiver of all or a portion of the non-federal match requirement on the basis of the grantee's written application submitted for the budget period and any supporting evidence included.

Request for Information

What are your thoughts on fiscal operations and management requirements, regulations, and TTA supports for AI/AN Head Start programs as outlined above? See below for more specific prompts to target feedback on fiscal operations.

K. Fiscal Operations

OHS invites comment on specific challenges or barriers recipients have experienced with these fiscal requirements, and others not listed, as well as any opportunities we can improve to better support tribes in fiscal management and oversight.

L. Early Childhood Systems

Tribal early childhood development programs that serve young children and their families, including Head Start, CCDF, and tribal Maternal, Infant, and Early Childhood Home Visiting (MIECHV), have separate funding sources, standards, regulations, and governance structures. Some tribes have shared that they have encountered challenges in collaborating across programs to develop a comprehensive birth to 5 approach to early care and education, while others have had success with collaboration and early childhood systems building.

ACF has engaged in efforts to support more coordinated and integrated tribal early childhood programs and systems, including the Tribal Early Learning Initiative (TELI). TELI is a partnership between ACF and tribes to better coordinate tribal early learning programs, create seamless systems for high-quality early childhood, raise the quality of services, and identify and break down barriers to collaboration and system improvement.

Request for Information

What are your thoughts on the early childhood systems requirements, regulations, and TTA supports for AI/AN Head Start programs as outlined above? See below for more specific prompts to target feedback on early childhood systems.

L. Early Childhood Systems

OHS understands that AI/AN Head Start programs have experienced both successes and barriers to collaboration with other early childhood system partners, including child care, home visiting, and other programs serving young children and their families. We welcome input regarding the provisions of the HSPPS that inhibit or promote collaboration to establishing seamless and integrated supports for families. We also welcome input on what policy guidance or TTA would be helpful in enabling tribes to better align and coordinate programs and build stronger early childhood systems.

M. Other Topics

Please describe any other OHS tribal regulations and processes that interfere with tribal nations' Head Start program implementation and/or policies, regulations or TTA supports not yet addressed in this RFI and proposed solution(s).

Megan Steel,

ACF Certifying Officer.

[FR Doc. 2024–05573 Filed 3–15–24; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0133]

Pharmacokinetics in Patients With Impaired Renal Function—Study Design, Data Analysis, and Impact on Dosing; 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 ''Pharmacokinetics in Patients with Impaired Renal Function—Study Design, Data Analysis, and Impact on Dosing.'' In general, drug development programs should be conducted so that when products are approved, the labeling provides appropriate dosing recommendations for patients with renal impairment. This guidance is intended to assist sponsors in the design and analysis of studies that assess the influence of impaired renal function on the pharmacokinetics (PK) and/or pharmacodynamics (PD) of an investigational drug and addresses how such information can inform the labeling. This guidance finalizes the draft guidance ''Pharmacokinetics in Patients with Impaired Renal Function—Study Design, Data Analysis, and Impact on Dosing'' issued on September 4, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on March 18, 2024.

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–2010–D–0133 for ''Pharmacokinetics in Patients with Impaired Renal Function—Study Design, Data Analysis, and Impact on Dosing.'' 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Martina Sahre, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO51/2114, Silver Spring, MD 20993–0002, 301–796–9659.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Pharmacokinetics in Patients with Impaired Renal Function—Study Design, Data Analysis, and Impact on Dosing.'' The kidneys are involved in the elimination of many drugs, where the degree of renal excretion of unchanged drug and/or metabolites is the net result of glomerular filtration, tubular secretion, tubular reabsorption, and to a lesser degree metabolism. If a drug is eliminated primarily through renal excretion, then impaired renal function often alters the drug's PK to an extent that a change in the dosage from that used in patients with normal renal function should be considered. Literature reports indicate that impaired renal function can alter some drug metabolism and transport pathways in the liver and gut, thus there is the potential for renal impairment to also affect drugs that are predominantly cleared nonrenally. For these reasons, it is important to characterize a drug's PK in subjects with impaired renal function to provide appropriate dosage recommendations.

The safety and effectiveness of a drug are generally established for specific dosage regimens in late-phase clinical trials that enroll patients from the intended target patient population. Sometimes, individuals with impaired renal function are explicitly excluded from participation in these trials. Drug development programs should include an early characterization of the effect of impaired renal function on a drug's PK, with the goal of enabling the inclusion of this population in late-phase trials by allowing appropriate prospective dosage adjustment.

This guidance finalizes the draft guidance of the same title issued on September 4, 2020 (85 FR 55303). Revisions to the draft guidance include an expansion of the section on renal replacement therapies, especially the language related to continuous renal replacement therapy. Further revisions include an edit to the classification stages for the purpose of enrolling into a stand-alone renal impairment study.

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 ''Pharmacokinetics in Patients with Impaired Renal Function—Study Design, Data Analysis, and Impact on Dosing.'' 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 (44 U.S.C. 3501–3521). The collections of information in 21 CFR 201.57 pertaining to certain prescription drug labeling have been approved under OMB control number 0910–0572. The collections of information in 21 CFR part 312 pertaining to the submission of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 pertaining to the submission of new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 pertaining to biologics license applications have been approved under OMB control number 0910–0338.

III. Electronic Access

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

Dated: March 12, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05683 Filed 3–15–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1054]

Manufacture of Batches in Support of Original New Animal Drug Applications, Abbreviated New Animal Drug Applications, and Conditional New Animal Drug Applications; 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 (GFI) #285 entitled ''Manufacture of Batches in Support of Original NADAs, ANADAs, and CNADAs.'' This draft guidance is intended to provide recommendations for the primary batches of drug product manufactured to support the approval or conditional approval of new animal drug products. This guidance is applicable to all original new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs), and their associated investigational new animal drug files (INADs) and generic investigational new animal drug files, respectively, as well as applications for conditional approval of new animal drugs (CNADAs).

DATES: Submit either electronic or written comments on the draft guidance by May 17, 2024 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–1054 for ''Manufacture of Batches in Support of Original NADAs, ANADAs, and CNADAs.'' 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 guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. 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.