afforded to the provider by the Medicaid State agency. Lastly, Medicaid State agencies must notify CMS when to terminate the withholding; *Form Number:* CMS–R–21 (OMB control number: 0938–0287); *Frequency:* Occasionally; *Affected Public:* State, local, or Tribal governments; *Number of Respondents:* 54; *Total Annual Responses:* 27; *Total Annual Hours:* 81. (For policy questions regarding this collection contact Stuart Goldstein at 410–786–0694.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* 1915(c) Home and Community-Based Services (HCBS) Waiver Application; *Use:* We use the application to review and adjudicate individual waiver actions. The application is also used by States to submit and revise their waiver requests. *Form Number:* CMS–8003 (OMB control number 0938–0449); *Frequency:* Yearly; *Affected Public:* State, local, or Tribal governments; *Number of Respondents:* 47; *Total Annual Responses:* 71; *Total Annual Hours:* 6,005. (For policy questions regarding this collection contact Ryan Shannahan at 410–786–0295.)

Dated: September 6, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–19500 Filed 9–8–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–3391]

Clinical Pharmacology Considerations for Peptide Drug Products; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Clinical Pharmacology Considerations for Peptide Drug Products.'' This guidance describes FDA's recommendations regarding clinical pharmacology considerations for peptide drug product development programs, including hepatic impairment, drug-drug interactions (DDIs), assessing QTc prolongation risk, and immunogenicity risk and impact on the pharmacokinetics (PK), safety, and efficacy assessment. The intent of this draft guidance, when finalized, is to assist industry in the conduct of these development programs.

DATES: Submit either electronic or written comments on the draft guidance by December 11, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2023–D–3391 for ''Clinical Pharmacology Considerations for Peptide Drug Products.'' 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: Daphne Guinn, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, *daphne.guinn@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Pharmacology Considerations for Peptide Drug Products.'' This draft guidance, when finalized, will represent FDA's current thinking on the conduct of certain clinical pharmacology studies during the development of peptide drug products.

The term ''peptide'' refers to any polymer composed of 40 or fewer amino acids. In general, if a peptide meets the definition of a drug and does not otherwise meet the statutory definition of a ''biological product'' or a ''device,'' it would be regulated as a drug under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and be subject to all the ''drug'' requirements under the FD&C Act and FDA's regulations, including the requirement that new drugs must be approved under section 505(c) of the FD&C Act before they can be marketed in interstate commerce. However, peptide drug products can have product characteristics that may be similar, in certain respects, to biological products, and as such, there are other FDA guidances on biological products that discuss scientific principles that could also be applicable to peptide drug products.

The ''Clinical Pharmacology Considerations for Peptide Drug Products'' draft guidance, when finalized, will provide recommendations to assist industry in the development of peptide drug products. Specifically, this guidance describes FDA's recommendations regarding clinical pharmacology considerations for peptide drug product development programs, including organ impairment, DDIs, assessing QTc prolongation risk, and immunogenicity risk and impact on PK, safety, and efficacy assessment. This guidance provides recommendations on when these assessments may be appropriate.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the current thinking of FDA on ''Clinical Pharmacology Considerations for Peptide Drug Products.'' 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 OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB Control No. 0910–0014. The collections of information in 21 CFR part 314 have been approved under OMB Control No. 0910–0001. The collections of information in 21 CFR part 201 have been approved under OMB Control No. 0910–0572.

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, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19456 Filed 9–8–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3681]

Request for Nominations of a Nonvoting Representative of the Interest of the Tobacco Manufacturing Industry on the Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for a nonvoting representative of the interests of the tobacco manufacturing industry to serve on the Tobacco Products Scientific Advisory Committee (TPSAC), in the Center for Tobacco Products. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups. A nominee may either be self-nominated or nominated by an organization. In addition, FDA is requesting that any industry organizations interested in participating in the selection of a nonvoting representative of the interests of the tobacco manufacturing industry to serve on the TPSAC, notify FDA in writing. Nominations will be accepted for either the representative to serve on TPSAC or for the selection group effective with this notice.

DATES: Nomination materials for prospective candidates should be sent to FDA by October 11, 2023. Concurrently, any industry organization interested in participating in the selection of an appropriate nonvoting member to represent the interests of the tobacco manufacturing industry must send a letter stating that interest to FDA by October 11, 2023 (see sections I and II of this document for further details).

ADDRESSES: All nominations for nonvoting representatives of the interests of the tobacco manufacturing industry may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm.*

All statements of interest from industry organizations interested in participating in the selection process of nonvoting representatives of the interests of the tobacco manufacturing industry nomination should be sent to Serina Hunter-Thomas (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373 (choose Option 5), email: *TPSAC@fda.hhs.gov.*

Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at: *https://www.fda.gov/AdvisoryCommittees/default.htm.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for a nonvoting representative of the interests of the tobacco manufacturing industry on the TPSAC.

I. General Description of the Committee Duties

The TPSAC advises the Commissioner of Food and Drugs (the Commissioner) or designee in discharging responsibilities related to the regulation of tobacco products. The TPSAC reviews and evaluates safety, dependence, or health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner.