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FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Pharmacology Considerations for Peptide Drug Products.'' This draft guidance, when finalized, will represent FDA's current thinking on the conduct of certain clinical pharmacology studies during the development of peptide drug products.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The ''Clinical Pharmacology Considerations for Peptide Drug Products'' draft guidance, when finalized, will provide recommendations to assist industry in the development of peptide drug products.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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the current thinking of FDA on ''Clinical Pharmacology Considerations for Peptide Drug Products.''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.

II. Nomination Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting representative of the interests of the tobacco manufacturing industry. Under part 14 (21 CFR part 14), nominations must include a current résumé or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available. Nominations must also specify the advisory committee for which the nominee is recommended and must acknowledge that the nominee is aware of the nomination unless self-nominated. The nomination should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

III. Selection Procedure

The Agency is also seeking names of organizations to participate in the selection of the nonvoting representative of the interests of the tobacco manufacturing industry. Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest in participating in the selection group, attaching a complete list of all organizations participating in selection; and a list of all non-voting nominees along with their current résumés. The letter will also state that it is the responsibility of the interested organizations on the selection group to confer with one another and to select a candidate and an alternative as backup, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the TPSAC. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*) and part 14, relating to advisory committees.

Dated: September 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19499 Filed 9–8–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0008]

Request for Nominations From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the Vaccines and Related Biological Products Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on the Vaccines and Related Biological Products Advisory Committee (VRBPAC) for the Center for Biologics Evaluation and Research notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the VRBPAC. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

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

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nominations should be sent via email to Sussan Paydar (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives must be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal at: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm.* 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.*

FOR FURTHER INFORMATION CONTACT: Sussan Paydar or Valerie Vashio, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1333, Silver Spring, MD 20993–0002, 202–657–8533, email: *CBERVRBPAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative(s) to the following advisory committee:

I. Vaccines and Related Biological Products Advisory Committee

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products that are intended for use in the prevention, treatment, or diagnosis of human diseases, and as required, any other products for which the Food and Drug Administration has regulatory responsibility. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products and makes appropriate recommendations to the Commissioner of Food and Drugs (the Commissioner).

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter via email stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a notification to each organization that has expressed an interest, attaching a complete list of all such organizations and a list of all nominees along with their current résumés. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no