Dated: August 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16889 Filed 8–6–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2832]

Request for Nominations From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nomination 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 a nonvoting industry representative to serve on the Vaccines and Related Biological Products Advisory Committee (VRBPAC) for the Center for Biologics Evaluation and Research (CBER) 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 *September 6, 2019,* (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by September 6, 2019.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nomination should be sent to Serina Hunter-Thomas (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: *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: *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6338, Silver Spring, MD 20993–0002, 240–402–5771, Fax: 301–595–1307, Serina.Hunter-Thomas@fda.hhs.gov.

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

I. CBER Advisory Committee

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 which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other products for which FDA 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 (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 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, attaching a complete list of all such organizations, as well as a list of all nominees along with their current resumes. 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 individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate, and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest 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 for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women, 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.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: July 31, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3369]

Evaluating the Clinical Pharmacology of Oligonucleotide Therapeutics; Establishment of a Public Docket; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to collect comments on evaluating the clinical pharmacology of oligonucleotide therapeutics. There are many unique clinical pharmacology considerations concerning the development of oligonucleotide therapeutics; however, for the purposes of this request, the Agency is specifically interested in