MD 20993, 301–796–8695, email: *Shivana.Srivastava@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative(s) to the Pediatric Advisory Committee:

I. General Description of the Committee Duties

The Committee reviews, evaluates, and makes recommendations to the Commissioner of Food and Drugs (the Commissioner) regarding (1) pediatric research conducted under sections 351, 409I, and 499 of the Public Health Service Act (42 U.S.C. 262, 284m, and 290b) and sections 501, 502, 505, 505A, 505B, 510(k), 515, and 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 355, 355a, 355c, 360(k), 360e, and 360j(m)); (2) identification of research priorities related to pediatric therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments of specific pediatric diseases or conditions; (3) the ethics, design, and analysis of clinical trials related to pediatric therapeutics (including drugs and biological products) and medical devices; (4) pediatric labeling disputes as specified in Public Law 107–109, Public Law 110–85, and Public Law 112–144; (5) pediatric labeling changes as specified in Public Law 107–109, Public Law 110–85, and Public Law 112–144; (6) adverse event reports for drugs studied under Public Law 107–109, Public Law 110–85, and Public Law 112–144; (7) any safety issues that may occur as specified in Public Law 107–109, Public Law 110–85, and Public Law 112–144; (8) any other pediatric issue or pediatric labeling dispute involving FDA-regulated products; (9) pediatric ethical issues including research involving children as subjects as specified in 21 CFR 50.54; and (10) any other matter involving pediatrics for which FDA has regulatory responsibility.

The Committee also advises and makes recommendations to the Secretary of Health and Human Services (the Secretary) (HHS) directly or to the Secretary through the Commissioner on research involving children as subjects that is conducted or supported by HHS as specified in 45 CFR 46.407.

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, 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 individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Nomination 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 resume, 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 individuals on its advisory committees regardless of their gender identification, religious affiliation, racial and ethnic identification, or disability status and therefore encourages nominations of appropriately qualified candidates from all 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: April 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09071 Filed 4–27–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0620]

Advisory Committee; Pharmaceutical Science and Clinical Pharmacology Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Pharmaceutical Science and Clinical Pharmacology Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the January 22, 2024, expiration date.

DATES: Authority for the Pharmaceutical Science and Clinical Pharmacology Advisory Committee will expire on January 22, 2024, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Rhea Bhatt, Division of Advisory Committee and Consultant Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993, 301–796–9001, email: *ACPS-CP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates scientific, clinical and technical issues related to the safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases, the quality characteristics which such

drugs purport or are represented to have, and as required, any other product for which FDA has regulatory responsibility, and make appropriate recommendations to the Commissioner. The Committee may also review Agency sponsored intramural and extramural biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development.

The Committee shall consist of a core of 14 voting members including two Chairpersons. Members and Chairpersons are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pharmaceutical sciences (pharmaceutical manufacturing, bioequivalence research, laboratory analytical techniques, pharmaceutical chemistry, physiochemistry, biochemistry, molecular biology, immunology, microbiology) and clinical pharmacology (dose-response, pharmacokinetics-pharmacodynamics, modeling and simulation, pharmacogenomics, clinical trial design, pediatrics and special populations and innovative methods in drug development), biostatistics, related biomedical and pharmacological specialties, current good manufacturing practices, and quality systems implementation. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees, representatives or Ex-Officio members. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include up to three non-voting representative members who are identified with industry interests. There may also be an alternate industry representative.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/human-drug-advisory-committees/pharmaceutical-science-and-clinical-pharmacology-advisory-committee* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: April 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09076 Filed 4–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2001–D–0067]

Providing Submissions in Electronic Format—Postmarketing Safety Reports; 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 ''Providing Submissions in Electronic Format—Postmarketing Safety Reports.'' This guidance provides general information pertaining to electronic submission of postmarketing safety reports (individual case safety reports (ICSRs), attachments to ICSRs (ICSR attachments), and other postmarketing safety reports) for certain human drugs, biological products, and combination products. This guidance finalizes the revised draft guidance entitled ''Providing Submissions in Electronic Format—Postmarketing Safety Reports,'' issued in June 2014.

DATES: The announcement of the guidance is published in the **Federal Register** on April 28, 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–2001–D–0067 for ''Providing Submissions in Electronic Format—Postmarketing Safety Reports.'' 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