

and privilege protections of the Patient Safety Act.

The CFER-DS is the first AHRQ Common Formats for Event Reporting that can be used across healthcare settings. It is designed to capture standardized, structured data to facilitate the reporting of diagnostic safety events for the purpose of learning about how to improve diagnostic safety and better support the diagnostic process.

The CFER-DS is not designed for frontline incident reporting. It is intended to facilitate the collection and organization of a basic set of meaningful data about diagnostic safety events that can be used, aggregated and analyzed for learning and improvement. Having a common frame of reference and standardized data elements makes shared learning possible at local, regional, and national levels. Users decide if and how to integrate collection of specific CFER data elements into their incident reporting systems and other existing work processes.

At this time, AHRQ is releasing the CFER-DS Version 1.0 Event Description and some supporting materials, including the Users' Guide and Form. A Sample Preliminary Clinician Event Report is also being made available as a convenience for optional use or adaptation as a supporting resource to the CFER-DS. Additional supporting documents and technical specifications for the CFER-DS (e.g., Data Dictionary, Flow Charts, Resources Workbook) are anticipated to be released in Fall 2022.

Information on how to comment on Common Formats is available at: http://www.qualityforum.org/Project_Pages/Common_Formats_for_Patient_Safety_Data.aspx.

Additional information about the AHRQ Common Formats can be obtained through AHRQ's PSO website: <https://psa.ahrq.gov/common-formats>.

Dated: June 3, 2022.

Marquita Cullom,
Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0618]

Advisory Committee; Drug Safety and Risk Management 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 Drug Safety and Risk Management 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 Drug Safety and Risk Management Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the May 31, 2024, expiration date.

DATES: Authority for the Drug Safety and Risk Management Advisory Committee will expire on May 31, 2024, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT:

Philip Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 240-762-8729, DSaRM@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services (HHS) and by the General Services Administration, FDA is announcing the renewal of the Drug Safety and Risk Management 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 information on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which FDA has regulatory responsibility. The Committee also advises the Commissioner regarding the scientific and medical evaluation of all information gathered by HHS and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken by HHS with regard to the marketing, investigation, and control of such drugs or other substances.

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or

designee from among authorities knowledgeable in the fields of risk communication, risk management, drug safety, medical, behavioral, and biological sciences as they apply to risk management, and drug abuse. 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 one non-voting representative member who is 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/drug-safety-and-risk-management-advisory-committee/drug-safety-and-risk-management-advisory-committee-charter> 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: June 3, 2022.

Lauren K. Roth,
Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0622]

Advisory Committee; Pulmonary-Allergy Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.