intended for use in the diagnosis, prevention, or treatment of human diseases, and, as required, any other product for which FDA has regulatory responsibility. BPAC also advises the Commissioner of Food and Drugs (the Commissioner) of its findings regarding screening and testing (to determine eligibility) of donors and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological products licenses, and on the quality and relevance of FDA's research program that provides the scientific support for regulating these agents.

BPAC will function at times as a medical device panel under the Federal Food, Drug, and Cosmetic Act (FD&C Act) Medical Device Amendments of 1976. As such, BPAC recommends classification of devices subject to its review into regulatory categories, recommends the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category, advises on formulation of product development protocols and reviews premarket approval applications for those devices to recommend changes in classification as appropriate, recommends exemption of certain devices from the application of portions of the FD&C Act, advises on the necessity to ban a device, and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

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 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. Nomination must include a current, complete résumé or curriculum vitae for each nominee, including current business address and telephone number, email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. 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 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.

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: March 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05358 Filed 3–15–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1155]

The Use of Published Literature in Support of New Animal Drug Approvals; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry #106 entitled ''The Use of Published Literature in Support of New Animal Drug Approvals.'' This guidance replaces existing guidance #106, ''The Use of Published Literature in Support of New Animal Drug Approvals,'' which FDA published in August 2000. It addressed the use of a single scientific article to support drug approval. This revision of the guidance document considers multiple uses of the scientific literature, including narrative reviews, systematic reviews, and meta-analyses to support approval of a new animal drug.

DATES: The announcement of the guidance is published in the **Federal Register** on March 16, 2023.

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–2021–D–1155 for ''The Use of Published Literature in Support of New Animal Drug Approvals.'' 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 guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Amey Adams, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0816, *Amey.Adams@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 20, 2022 (87 FR 23523), FDA published the notice of availability for a draft guidance entitled ''The Use of Published Literature in Support of New Animal Drug Approvals'' giving interested persons until June 21, 2022, to comment on the draft guidance. FDA received several comments on the draft guidance, and those comments were considered as the guidance was finalized. For example, one comment requested that we further clarify and discuss the potential utility of published studies conducted outside of the United States; we added such language to the final guidance. In addition, other editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated April 2022.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''The Use of Published Literature in Support of New Animal Drug Approvals.'' 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: March 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05333 Filed 3–15–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–1105]

Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers; 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 ''Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers.'' The draft guidance provides information for sponsors, clinical investigators, institutional review boards (IRBs), contract research organizations (CROs), and other interested parties on the use of electronic systems, electronic records, and electronic signatures in clinical investigations of foods, medical products, tobacco products, and new animal drugs under FDA regulations. This draft guidance revises the draft guidance for industry issued in June 2017 entitled ''Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR part 11—Questions and Answers'' and, when finalized, will supersede the guidance for industry entitled ''Computerized Systems Used in Clinical Investigations'' (May 2007).

DATES: Submit either electronic or written comments on the draft guidance by May 15, 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: