TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB—Continued

Title of collection	OMB control No.	Date approval expires
Individual Patient Expanded Access Applications	0910–0814	5/31/2022
Electronic Forma for Submissions; Promotional labeling and Advertising Materials for Human Prescription Drugs	0910–0870	5/31/2022
Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation	0910–0456	6/30/2022
Electronic Submission of Medical Device Registration and Listing	0910–0625	6/30/2022
Antimicrobial Animal Drug Distribution Reports and Recordkeeping	0910–0659	6/30/2022
Obtaining Information for Evaluating Nominated Bulk Drug Substances for Use in Compounding Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act	0910–0871	6/30/2022

Dated: July 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15626 Filed 7–22–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0424]

Final Guidance for Industry and FDA Staff on Postmarketing Safety Reporting for Combination Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry and FDA staff entitled ''Postmarketing Safety Reporting for Combination Products Guidance for Industry and FDA Staff.'' The guidance describes and explains the final rule on postmarketing safety reporting (PMSR) for combination products, issued on December 20, 2016, and provides recommendations for complying with the PMSR requirements as well as hypothetical scenarios that illustrate how to comply with certain PMSR requirements.

DATES: The announcement of the guidance is published in the **Federal Register** on July 23, 2019.

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: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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 below (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–2008–N–0424 for ''Postmarketing Safety Reporting for Combination Products Guidance for Industry and FDA Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *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 *http://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.gpo.gov/fdsys/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 *http://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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)). Submit written requests for a single hard copy of the guidance document entitled ''Postmarketing Safety Reporting for Combination

Products Guidance for Industry and FDA Staff'' to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 32, Room 5129, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Burns or John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993–0002, 301–796–8930.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Postmarketing Safety Reporting for Combination Products Guidance for Industry and FDA Staff.'' The guidance provides general information on combination products; how FDA regulates combination products; a summary of the combination product PMSR final rule (21 CFR part 4, subpart B); an overview of which entities are subject to the final rule and what safety reporting requirements apply to such entities; detailed discussion of specific combination product PMSR report types; guidance on where, how, and when to submit PMSR reports to FDA; and hypothetical scenarios that illustrate how to comply with certain combination product PMSR requirements.

FDA carefully considered the comments received on the draft guidance, and revised the guidance as appropriate in response to the comments. Combination PMSR information, including examples to illustrate how to report combination production information in electronic reporting systems, is also available on FDA's website at *https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products.* FDA encourages combination product applicants to contact the lead Center for their combination product and/or the Office of Combination Products if they have questions on PMSR compliance.

II. Significance of Guidance

This 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 Postmarketing Safety Reporting for Combination 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. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons with access to the internet may obtain the guidance document at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/combination-products-guidance-documents.*

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 314.80(c) and (e), as well as for 21 CFR 314.81(b) are approved under OMB control numbers 0910–0001, 0910–0230, and 0910–0291. The information collection provisions for 21 CFR 600.80 and 600.81 are approved under OMB control number 0910–0308. Those for 21 CFR 606.170 are approved under OMB control number 0910–0116. Those for 21 CFR 606.171 are approved under OMB control number 0910–0458. The information collection provisions for 21 CFR 803.50, 803.53, and 803.56 are approved under OMB control numbers 0910–0291 and 0910–0437. The information collection provisions for 21 CFR 806.10 and 806.20 are approved under OMB control number 0910–0359. The information collection provisions for 21 CFR 4.102, 4.103, and 4.105 are approved under OMB control number 0910–0834.

Dated: July 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15595 Filed 7–22–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Drug Abuse.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Drug Abuse.

Date: September 5, 2019.

Closed: 9:00 a.m. to 10:15 a.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852.

Open: 10:30 a.m. to 4:30 p.m.

Agenda: This portion of the meeting will be open to the public for announcements and reports of administrative, legislative, and program developments in the drug abuse field.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Susan R.B. Weiss, Ph.D. Director, Division of Extramural Research, Office of the Director, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, NSC, Room 5274, MSC 9591, Rockville, MD 20892, 301–443–6487, *sweiss@nida.nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.drugabuse.gov/NACDA/NACDAHome.html,* where an agenda and