and effectiveness reach patients as quickly as possible, we have modified the PMA filing guidance. In this guidance entitled, ''Acceptance and Filing Reviews for Premarket Approval Applications (PMAs),'' we have separated the requirements for PMA filing into: (1) Acceptance criteria and (2) filing criteria. Acceptance review involves an early assessment of the completeness of the application, and informing the applicant in a written response within the first 15 calendar days of receipt of the application whether any administrative elements are missing, and if so, identifying the missing administrative element(s).

In order to enhance the consistency of our acceptance and filing decisions and to help applicants understand the types of information FDA needs to conduct a substantive review of a PMA, this guidance and associated checklist clarify the necessary elements and contents of a complete PMA application. The process we outline is applicable to all devices reviewed in a PMA application. Acceptance and filing decisions will be made for all original PMA applications and panel-track PMA supplements.

This guidance is not significantly different from the 2003 PMA guidance document. The ''preliminary questions'' remain the same and the ''filing review questions'' have been separated into ''acceptance decision questions'' (i.e., is the file administratively complete) and ''filing decision questions'' (i.e., are data consistent with protocol, final device design, and proposed indications). In addition, it should be noted that this document is focused on the regulatory and scientific criteria for making an ''Accept'' or ''Refuse to Accept'' decision as well as ''File'' or ''Not File'' decision for a PMA. It specifically does not alter the following administrative aspects of the PMA filing process: (1) The time frame for the filing review phase (i.e., 45 days); (2) the processes for document tracking, distribution, and handling; and (3) the procedures for assembling the review team and setting up the filing meeting.

In the **Federal Register** of July 31, 2012 (77 FR 45357), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by September 14, 2012. Nine comments were received with multiple recommendations pertaining to the administrative processes and policies regarding acceptance and filing review decisions. In response to these comments, FDA revised the guidance document to clarify the processes and policies as appropriate. This guidance supersedes the guidance entitled ''Guidance for Industry and FDA Staff Premarket Approval Application Filing Review,'' dated May 1, 2003.

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 Agency's current thinking on acceptance and filing reviews for PMAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov* or from the CBER internet site at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*. To receive ''Acceptance and Filing Reviews for Premarket Approval Applications (PMAs),'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1792 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to currently 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 part 814, subpart B, have been approved under OMB control number 0910–0231.

V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov*. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Dated: December 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–31476 Filed 12–31–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1056]

Guidance for Industry and Food and Drug Administration Staff; eCopy Program for Medical Device Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''eCopy Program for Medical Device Submissions.'' The purpose of the guidance is to explain the new electronic copy (eCopy) Program for medical device submissions, which is intended to improve the efficiency of the review process by allowing for the immediate availability of an electronic version for review rather than relying solely on the paper version. The guidance describes how FDA has implemented the eCopy Program under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This guidance also provides the standards for a valid eCopy under the FD&C Act and identifies the submission types that must include an eCopy in accordance with these standards for the submission to be processed and accepted for review by FDA. This final guidance will be considered in effect on January 1, 2013, or at the time of publication, whichever is later.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''eCopy Program for Medical Device Submissions'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send

one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:
Samie Allen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1533, Silver Spring, MD 20993–0002, 301–796–6055; or
Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry and FDA staff entitled ''eCopy Program for Medical Device Submissions.'' This guidance explains the new eCopy Program for medical device submissions. This final guidance will be considered in effect on January 1, 2013, or at the time of publication, whichever is later. After this date, submission of an eCopy for a medical device submission is no longer voluntary. Section 745A(b) of the FD&C Act, added by section 1136 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), requires the submission of an eCopy of certain device submissions after issuance of final guidance. This guidance describes how FDA has implemented the eCopy Program under section 745A(b) of the FD&C Act. The inclusion of an eCopy is expected to improve the efficiency of the review process by allowing for the immediate availability of an electronic version for review rather than relying solely on the paper version.

The eCopy Program is not intended to impact (reduce or increase) the type or amount of data the applicant includes in a submission to support clearance or approval. An eCopy is defined as an exact duplicate of the paper submission, created and submitted on a compact disc, digital video disc, or flash drive, accompanied by a copy of the signed cover letter and the complete paper submission.

In the **Federal Register** of October 17, 2012 (77 FR 63837), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by November 16, 2012. Eight comments were received and in general were supportive of the eCopy Program. However, the comments contained multiple recommendations pertaining to the organization of the guidance and requests for clarification on details such as how many copies are needed for each submission type, for what types of submissions an eCopy is required, the necessity for a signed cover letter, how eCopy processing is conducted, when a submission begins the review process, and how to interpret some of the standards in the Attachment. In response to these comments, FDA revised the guidance document to clarify the primary points of confusion identified, and restructured the information for better readability.

II. Significance of Guidance

In section 745A(b), Congress granted explicit statutory authorization to FDA to implement the statutory eCopy requirement by providing standards, criteria for waivers, and exemptions in guidance. To the extent that this document provides requirements under section 745A(b)(2)(A) of the FD&C Act (i.e., standards, criteria for waivers, and exemptions), indicated by the use of the words *must* or *required,* this document is not subject to the usual restrictions in FDA's good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities. (See 21 CFR 10.115(d).)

However, this document also contains guidance on implementing the eCopy Program. To the extent that this guidance describes recommendations that are not standards, criteria for waivers, or exemptions under section 745A(b)(2), it is being issued in accordance with FDA's good guidance practices regulation (21 CFR 10.115). Such parts of this guidance represent the Agency's current thinking on this topic, and do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used for these recommendations if such an approach satisfies the requirements of the applicable statutes and regulations. The use of the word *should* in this guidance means that something is suggested or recommended, but not required. This final guidance contains both binding and nonbinding provisions.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*. To receive ''eCopy Program for Medical Device Submissions,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1797 to identify the guidance you are requesting.

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 part 807, subpart E, have been approved under OMB control number 0910–0120 (510(k)); the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078 (Investigational Device Exemptions); the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231 (Premarket Approval); the collections of information in section 513(g) of the FD&C Act (21 U.S.C. 360c(g)) have been approved under OMB control number 0910–0705 (513(g)); the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control numbers 0910–0332 and 0910–0661 (Humanitarian Use Devices); and the collections of information in section 564 of the FD&C Act (21 U.S.C. 360bbb–3) have been approved under OMB control number 0910–0595 (Emergency Use Authorization).

V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov*. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and

will be posted to the docket at *http://www.regulations.gov*.

Dated: December 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–31478 Filed 12–31–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Advisory Committees; Tentative Schedule of Meetings for 2013

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a tentative schedule of forthcoming meetings of its public advisory committees for 2013. During 1991, at the request of the Commissioner of Food and Drugs (the Commissioner), the Institute of Medicine (the IOM) conducted a study of the use of FDA's advisory committees. In its final report, one of the IOM's recommendations was for the Agency to publish an annual tentative schedule of its meetings in the **Federal Register**. This publication implements the IOM's recommendation.

FOR FURTHER INFORMATION CONTACT: Teresa L. Hays, Advisory Committee Oversight and Management Staff (HF–4), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5290, Silver Spring, MD 20993, 301–796–8220.

SUPPLEMENTARY INFORMATION: The IOM, at the request of the Commissioner, undertook a study of the use of FDA's advisory committees. In its final report in 1992, one of the IOM's recommendations was for FDA to adopt a policy of publishing an advance yearly schedule of its upcoming public advisory committee meetings in the **Federal Register**; FDA has implemented this recommendation. The annual publication of tentatively scheduled advisory committee meetings will provide both advisory committee members and the public with the opportunity, in advance, to schedule attendance at FDA's upcoming advisory committee meetings. Because the schedule is tentative, amendments to this notice will not be published in the **Federal Register**. However, changes to the schedule will be posted on the FDA advisory committees' Internet site located at *http://www.fda.gov/AdvisoryCommittees/default.htm*. FDA will continue to publish a **Federal Register** notice 15 days in advance of each upcoming advisory committee meeting, to announce the meeting (21 CFR 14.20).

The following list announces FDA's tentatively scheduled advisory committee meetings for 2013. You may also obtain up-to-date information by calling the Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area) or on the FDA Internet Web site under our 2013 tentative scheduled meeting listing at *http://www.fda.gov/AdvisoryCommittees/Calendar/ucm153468.htm*.

TABLE 1

Committee name	Tentative date(s) of meeting(s)
OFFICE OF THE COMMISSIONER	
Pediatric Advisory Committee	March 14–15, September 19–20.
Risk Communication Advisory Committee	February 11–12, April 29–30, August 15–16, December 16–17.
Science Board to FDA	February 27, June 24, November 20.
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH	
Allergenic Products Advisory Committee	November 5–6.
Blood Products Advisory Committee	February 12–13, April 8–9, August 1–2.
Cellular, Tissue and Gene Therapies Advisory Committee	January 15, April 17–18, June 27–28, October 24–25.
Transmissible Spongiform Encephalopathies Advisory Committee	March 14–15.
Vaccines and Related Biological Products Advisory Committee	February 27, May 8–9 or July 17–18 (Backup date), September 18–19, November 13–14.
CENTER FOR DRUG EVALUATION AND RESEARCH	
Anesthetic and Analgesic Drug Products Advisory Committee	Date(s), if needed, to be determined.
Anti-Infective Drugs Advisory Committee	Date(s), if needed, to be determined.
Antiviral Drugs Advisory Committee	May and October dates to be determined.
Arthritis Advisory Committee	July or August and fall dates to be determined.
Cardiovascular and Renal Drugs Advisory Committee	April 17 and other date(s) to be determined.
Dermatologic and Ophthalmic Drugs Advisory Committee	Date(s), if needed, to be determined.
Drug Safety and Risk Management Advisory Committee	January 24–25, March 5.
Endocrinologic and Metabolic Drugs Advisory Committee	January 10, July, and August dates to be determined.
Gastrointestinal Drugs Advisory Committee	March 19 and other date(s) to be determined.
Medical Imaging Drugs Advisory Committee	February 14 and May date to be determined.
Nonprescription Drugs Advisory Committee	Date(s), if needed, to be determined.
Oncologic Drugs Advisory Committee	April 5, May, June, July, September date(s) to be determined.
Pharmacy Compounding Drugs Advisory Committee	Date(s), if needed, to be determined.
Peripheral and Central Nervous System Drugs Advisory Committee	May 22.
Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.	Date(s), if needed, to be determined.
Psychopharmacologic Drugs Advisory Committee	Date(s), if needed, to be determined.
Pulmonary-Allergy Drugs Advisory Committee	January 29–30, March 7.
Advisory Committee for Reproductive Health Drugs	March 4–5, July 9.