The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for progesterone gel. 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. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: October 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27816 Filed 10–30–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3787]

Information To Support a Claim of Electromagnetic Compatibility of Electrically Powered Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices.'' This guidance describes the types of information that should be provided to support a claim of electromagnetic compatibility (EMC) in a premarket submission for an electrically powered medical device. Electromagnetic disturbance is electronic product radiation that may interfere with the performance of an electrically powered medical device in its intended environment (*i.e.,* cause an electromagnetic interference (EMI)). EMC assessment helps to ensure that a device is able to function in its intended environment without introducing excessive electromagnetic disturbances that might interfere with other devices. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 17, 2015.

ADDRESSES: You may submit comments 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 (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2015–D–3787 for ''Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices.'' 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 Division of Dockets Management 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 Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Donald Witters, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 62, Rm. 1130, Silver Spring, MD 20993–0002, 301–796–2483.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance to provide FDA's current thinking on the types of information that should be provided in a premarket submission to support a claim of electromagnetic compatibility for an electrically powered medical device. EMI is a hazard with associated risk for electrically powered medical devices. EMC assessment can help to ensure that the risks associated with performance degradation of electrically powered medical devices due to EMI are adequately mitigated.

The draft guidance includes information consistent with specifications described in FDA-recognized consensus national or international standards for EMC such as in the International Electrotechnical Commission (IEC) 60601–1–2: Edition 3: 2007–03, Medical Electrical Equipment—Part 1–2: General Requirements for Basic Safety and Essential Performance—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests; IEC 60601–1–2: Edition 4.0: 2014–01, Medical Electrical Equipment, Part 1–2: General Requirements for Basic Safety and Essential Performance—Collateral Standard: Electromagnetic Disturbances—Requirements and Tests; Association for the Advancement of Medical Instrumentation (AAMI)/American National Standards Institute (ANSI)/IEC 60601–1–2: 2007/(R) 2012 Medical Electrical Equipment—Part 1–2: General Requirements for Basic Safety and Essential Performance—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests; and AAMI/ANSI/IEC 60601–1–2: 2014, Medical Electrical Equipment—Part 1–2: General Requirements for Basic Safety and Essential Performance—Collateral Standard: Electromagnetic Disturbances—Requirements and Tests Standards that sponsors and manufacturers of electrically powered medical devices often reference. This draft guidance is intended to help ensure that clear and consistent information is provided in premarket submissions regarding medical device EMC and to facilitate the review of submissions with EMC claims.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on information that should be provided to support claims of electromagnetic compatibility of electrically powered medical devices. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400057 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft 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 814 have been approved under OMB control number 0910–0231. The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120. The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078. The collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332. The collections of information in sections 520(m) and 515A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j and 21 U.S.C. 360e–1, respectively) and 613(b) of Food and Drug Administration Safety and Innovation Act have been approved under OMB control number 0910–0661.

Dated: October 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27818 Filed 10–30–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–4040–New–60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit a new Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before January 4, 2016.

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690–6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier HHS–OS–4040–New–60D for reference.

Information Collection Request Title: DATA Act Sec. 5. ''Simplifying Federal Award Reporting'' Grants Pilot.

Abstract: Public Law 113–101, The Digital Accountability and Transparency Act of 2014 (DATA Act) expands the Federal Funding Accountability and Transparency Act of 2006 by increasing accountability and transparency in Federal spending. Section 5 of the DATA Act (''Sec. 5. Simplifying Federal Award Reporting'') tasks the Director of the Office of Management and Budget (OMB) to establish a pilot program (Sec. 5 (b)).

OMB has designated the Department of Health and Human Services (HHS) as the executing agent of the pilot program. Within HHS, the DATA Act Program Management Office (PMO) (DAP) has been established under the Office of the