TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR Section	No. of recordkeepers	No. of records per recordkeeper	Total annual records	Average burden per record-keeping	Total hours
Reprocessing Procedures 212.20(c); 212.71(d).	129	1	129	1	129
Reprocessing Procedures 212.20(c); 212.90(a).	129	1	129	1	129
Distribution Records 212.90(b)	129	501	64,640	0.25 (15 mins.)	16,160
Complaints 212.20(c); 212.100(a)	129	1	129	1	129
Complaints 212.100(b), 212.100(c)	129	1	129	0.5 (30 mins.)	65
Total					115,435

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	No. of respondents	Annual frequency of disclosure	Total annual disclosures	Hours per disclosure	Total hours
Sterility Test Failure Notices 212.70(e)	129	0.25	32	1	32

[1] There are no capital costs or operating and maintenance costs associated with this information collection.

Dated: December 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–32685 Filed 12–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1021]

Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2016 Proposed Guidance Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the Web site location where the Agency will post two lists of guidance documents that the Center for Devices and Radiological Health (CDRH or the Center) intends to publish in Fiscal Year (FY) 2016. In addition, FDA has established a docket, where interested persons may comment on the priority of topics for guidance, provide comments and/or propose draft language for those topics, suggest topics for new or different guidance documents, comment on the applicability of guidance documents that have issued previously, and provide early input to support guidances that will be developed.

DATES: Although you can comment on any guidance at any time, submit either electronic or written comments by February 29, 2016.

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–N–1021 for ''Medical Device User Fee and Modernization Act; Notice to Public of Web site Location of Fiscal Year 2016 Proposed Guidance Development.'' 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.

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration,10903 New Hampshire Ave., Bldg. 66, rm. 5456, Silver Spring, MD 20993–0002, 301–796–6353.

SUPPLEMENTARY INFORMATION:

I. Background

During negotiations on the Medical Device User Fee Amendments of 2012 (MDUFA III), Title II, Food and Drug Administration Safety and Innovation Act (Pub. L. 112–114), FDA agreed to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. Among these commitments included:

- Annually posting a list of priority medical device guidance documents that the Agency intends to publish within 12 months of the date this list is published each fiscal year (the ''A-list'') and
- annually posting a list of device guidance documents that the Agency intends to publish, as the Agency's guidance-development resources permit each fiscal year (the ''B-list'').

FDA invites interested persons to submit comments on any or all of the guidance documents on the lists as explained in 21 CFR 10.115(f)(5). FDA has established the docket number (FDA–2012–N–1021) where comments on the FY 2016 lists, draft language for guidance documents on those topics, suggestions for new or different guidances, and relative priority of guidance documents may be submitted and shared with the public (see **ADDRESSES**). FDA believes this docket is an important tool for receiving information from interested persons and will update these lists annually on FDA's Web site at the beginning of each fiscal year from 2013 to 2017. FDA anticipates that feedback from interested persons, will allow CDRH to better prioritize and more efficiently draft guidances.

In addition to posting the lists of prioritized device guidance documents, FDA has committed to updating its Web site in a timely manner to reflect the Agency's review of previously published guidance documents; including, the deletion of guidance documents that no longer represent the Agency's interpretation of or policy on a regulatory issue and notation of guidance documents that are under review by the Agency.

Fulfillment of these commitments will be reflected through the issuance of updated guidance on existing topics, removal of guidances that that no longer reflect FDA's current thinking on a particular topic, and annual updates to the A-list and B-list announced in this notice.

II. CDRH Guidance Development Initiative

On June 5, 2014, CDRH held a public workshop to provide stakeholders (*e.g.,* industry, academia, public health advocacy groups, and other interested persons) an opportunity to actively engage with Center representatives about the guidance development process, provide transparency into guidance priority development, promote dialogue on guidance process improvements, and generate ideas for assessing the impact of guidance (Ref. 1). The workshop also provided a forum to discuss best practices and public participation in guidance development. CDRH carefully considered the comments and suggestions provided by stakeholders.

At the 2014 workshop, stakeholders requested that draft guidance documents be more clearly identified as ''draft'' to indicate to CDRH stakeholders and staff that they are not for implementation. CDRH revised its templates for new draft guidance documents by adding the watermark ''DRAFT'' to all pages in order to more conspicuously mark the guidance as not for implementation. CDRH implemented the use of the new templates effective August 6, 2014, and continues to use these templates.

Stakeholders also recommended that CDRH's guidance documents Web page (*http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*) list draft guidances separately from those that had been finalized. CDRH revised its guidance document Web page to include a left navigation item for ''Draft Guidance.'' In addition, CDRH removed draft guidance documents from the office guidance document lists and separated the link to ''Recent Medical Device Guidance Documents'' into two separate links: ''Recent Medical Device Final Guidance Documents'' and ''Recent Medical Device Draft Guidance Documents.''

CDRH is aware of draft guidance documents yet to be finalized. Therefore, in order to assure the timely completion or re-issuance of draft guidances in FY 2015, CDRH committed to performance goals for current and future draft guidance documents. For draft guidance documents issued after October 1, 2014, CDRH committed to finalize, withdraw, reopen the comment period or issue another draft guidance on the topic for 80 percent of the documents within 2 years of the close of the comment period and for the remaining 20 percent, within 5 years. In FY 2015, CDRH has withdrawn 14 of 20 draft guidances issued prior to October 1, 2009, and has been continuing to work towards finalizing the remaining draft guidances. Furthermore, in FY 2016, CDRH will finalize, withdraw, or reopen the comment period for 50 percent of existing draft guidances issued prior to October 1, 2010, CDRH expects to renew or modify, as appropriate, these performance goals in FY 2017 and subsequent years.

A. Earlier Stakeholder Involvement in Guidance Development

At the 2014 workshop, stakeholders also expressed a desire to be involved earlier in the guidance development process. CDRH representatives discussed various ways in which the Center currently encourages participation by external stakeholders in the guidance development process. In the case of emerging technologies, CDRH uses ''leapfrog'' guidances to provide initial recommendations regarding the type of information that would be appropriate in the review of these emerging technologies. Input from external stakeholders help CDRH

formulate its initial thinking on the data necessary to support marketing approval, clearance, or oversight of these devices. In FY 2015, CDRH issued two leapfrog draft guidances, ''Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices'' (Ref. 2) and Radiation Biodosimetry Devices (Ref. 3). For the Premarket Studies of Implantable MIGS Device guidance document, early stakeholder input was obtained through discussions with glaucoma specialists identified by the American Glaucoma Society through the Network of Experts (*http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/ucm289534.htm*), as well as through a workshop cosponsored with the American Glaucoma Society on February 26, 2014 (Ref. 4). In addition, early stakeholder feedback was obtained at a public workshop for the Radiation Biodosimetry Devices guidance document (Ref. 5).

Additionally, in FY 2015, in anticipation of guidance documents expected to be developed, CDRH sought stakeholder input regarding Patient Matched Instrumentation for Orthopedics, Medical Devices Intended for Aesthetic Use, and Dual 510(k) and Clinical Laboratory Improvement Amendments Act (CLIA) Waiver by Application. The feedback received has been considered in the development of these guidances and CDRH has included the Dual 510(k) and CLIA Waiver by Application guidance and Patient Matched Instrumentation for Orthopedics on the FY2016 B-List.

CDRH is posing the following questions to interested persons for consideration and comment, so that relevant future draft guidances on these technologies can be as complete and useful as possible. We will carefully consider the comments received in the development of new guidance documents and incorporate the information where appropriate. CDRH believes that public input during guidance development and after a draft guidance is issued on the topic will lead to a comprehensive and informed final guidance on the Agency's policy for the technologies and processes in the following list:

1. Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices

EMC assessment is a vital part of ensuring that risks associated with performance degradation of electrically-powered medical devices associated with electromagnetic interference are adequately addressed. CDRH recently published a short draft guidance entitled ''Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices'' (Ref. 6) to provide a framework for promoting consistent submission and review of EMC information in premarket submissions. In addition, CDRH plans to also draft a more detailed guidance on this topic guidance to provide more comprehensive information and transparency to stakeholders regarding the information necessary to support an EMC claim. FDA invites comments on the following questions:

a. There has been increasing use of electromagnetic emitters (*e.g.,* radio-frequency identification, electronic article surveillance gates, metal detectors) in the environments where medical devices operate. What methods are used to determine EMC of devices exposed to these common emitters?

b. Given that basic safety, as defined in the IEC 60601–1 family of standards, does not include effectiveness, how is device performance evaluated differently than device safety for EMC? Specifically, are pass/fail criteria chosen such that they will address both performance and safety for each EMC test? Alternatively, are safety and performance tested separately?

c. When networks (wired or wireless) are determined to be necessary for device performance, how are they included as a system when tested for EMC?

d. The use of ''third party'' components can significantly affect the EMC of the medical device system. How are device systems evaluated for EMC when off-the-shelf components such as smartphones, tablets, or PCs are intended to be used in the device system?

e. Medical devices, like most electronic products, go through various design changes that can affect the EMC of the device system. The changes or modifications can occur after initial EMC testing. What factors and methods are used to determine how device changes or modifications (*e.g.,* software, firmware, hardware) will affect EMC and how is it determined when partial or complete EMC re-testing of a device is needed?

f. The use of magnetic resonance (MR) imaging technology on medical device users and patients is increasing. MR imaging incorporates very strong magnetic and electric fields that can have very significant effects on the safety and effectiveness of medical devices, especially electrically active devices. How is MR safety and compatibility addressed for electrically active medical devices intended for use in the MR environment? How is MR safety addressed (*e.g.* labeling or other) for electrically active medical devices not intended for use in the MR environment?

g. Several medical device EMC consensus standards specify the information to be conveyed to the user regarding device EMC. Is this information sufficient? If not, what additional type of information is typically provided to help the user manage the risks associated with medical device EMC and how is this information conveyed?

2. Utilizing Animal Studies To Evaluate the Safety of Organ Preservation Devices and Solutions

While the national transplant waiting list continues to grow, rates of donation and transplant remain stagnant. On average, 22 people die each day waiting for a transplant. The dire deficit in organ transplants has propelled a new wave of innovation in perfusion-based organ preservation technologies. With such innovation also comes the challenge of demonstrating that these new technologies, when evaluated in animal models, are sufficiently safe for early clinical experience.

After animal organs undergo preservation using a new organ transport device or solution, there are generally two models to assess post-reperfusion injury: (1) An in vivo model in which the organ is transplanted into a surrogate recipient animal and (2) an ex vivo model in which the organ is reperfused under simulated transplant conditions. FDA intends to develop guidance to provide recommendations for utilizing both in vivo and ex vivo models to evaluate emerging organ preservation technologies. Prior to drafting our recommendations in a future guidance document, FDA invites comments on the following questions:

a. What are the potential limitations of an ex vivo model in assessing reperfusion injury, and how can these limitations be mitigated? In addition to markers for cell injury and function, histology, and the use of allogeneic blood during reperfusion, what measures can be taken to improve the data generated in an ex vivo model?

b. In an in vivo model, what are strategies to limit confounding factors, such as immunological responses and hemodynamic instability, from affecting the assessment of device-related reperfusion injury?

c. Is there a perceived hierarchy of evidence regarding data obtained from an ex vivo model and those obtained from an in vivo model? Or rather, is it

more judicious to view the two models as complements of each other?

d. What role does the risk of the device play in the utilization of in vivo and ex vivo models? Regarding specific experimental parameters (*e.g.,* length of preservation, total ischemic time), under what circumstances is it appropriate to test the worst-case scenario?

e. What are the organ-specific challenges in developing in vivo and ex vivo models to assess reperfusion injury?

f. What approaches would improve the in vivo and ex vivo study designs to ensure the generation of sufficient, meaningful data while limiting the number of animals used in such studies?

B. Stakeholder Feedback To Enhance the CDRH Guidance Program

In addition, to enhance the CDRH guidance program, CDRH invites interested persons to comment on the following questions:

a. The cover page of each guidance document includes contact information for questions regarding the guidance, and a list of CDRH Offices that have generally contributed to the drafting of the guidance. Is the list of CDRH Offices involved in the drafting of the guidance informative? What other administrative information should be included on the cover page?

b. CDRH is committed to the continual improvement of the quality of guidance documents and we are seeking to identify examples of quality guidance documents. Are there specific guidance documents published in the past 5 years that were particularly informative and helpful that could serve as models for future guidance documents? Please provide the title of the guidance documents and briefly describe what specific aspects were informative and helpful?

c. Has the enhanced Guidance Document Search feature on the FDA Web site (*http://www.fda.gov/RegulatoryInformation/Guidances/default.htm*) improved searchability of guidances? Are there any suggestions for how the search feature could be improved?

C. Applicability of Previously-Issued Final Guidance

CDRH has issued over 1,000 guidance documents to provide stakeholders with the Agency's thinking on numerous topics. Each guidance reflected the Agency's current position at the time that it was issued. However, the guidance program has issued these guidances over a period greater than 20 years, raising the question of how current do previously issued final guidances remain? CDRH has resolved to address this concern through a staged review of previously issued final guidances in collaboration with stakeholders.

At the Web site where CDRH has posted the ''A-list'' and ''B-list'' for FY 2016, CDRH has also posted a list of final guidance documents that issued in 2006, 1996, 1986, and 1976.[1]

The Center is interested in external feedback on whether any of these final guidances should be revised or withdrawn. In addition, for guidances that are recommended for revision, information explaining the need for revision, such as, the impact and risk to public health associated with not revising the guidance, would also be helpful as the Center considers potential action with respect to these guidances. CDRH intends to provide these lists of previously-issued final guidances annually through FY 2025 so that by 2025, FDA and stakeholders will have assessed the applicability of all guidances older than 10 years. For instance, in the annual notice for FY 2017, CDRH expects to provide a list of the final guidance documents that issued in 2007, 1997, 1987, and 1977; the annual notice for FY 2018 is expected to provide a list of the final guidance documents that issued in 2008, 1998, 1988, and 1978, and so on. CDRH will consider the comments received from this retrospective review when determining priorities for updating guidance documents, and will revise these as resources permit. During FY 2015, CDRH received comments regarding guidances issued in 2005, 1995, and 1985, and is considering further actions on specific guidances in response to comments received.

Under the Good Guidance Practices regulation at § 10.115(f)(4), the public may, at any time, suggest that CDRH revise or withdraw an already existing guidance document. The suggestion should clearly explain why the guidance document should be revised or withdrawn and, if applicable, how it should be revised. Interested persons are requested to examine the list of previously issued final guidances provided by CDRH on the annual agenda Web site but feedback on any guidance is appreciated.

[1] The retrospective list of final guidances does not include: (1) Documents that are not guidances but were inadvertently categorized as guidance such as scientific publications, advisory opinions, and interagency agreements; (2) guidances actively being revised by CDRH; and (3) special controls documents.

III. Web Site Location of Guidance Lists

This notice announces the Web site location of the document that provides the A and B lists of guidance documents, which CDRH is intending to publish during FY 2016. To access these two lists, visit FDA's Web site at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm467223.htm.* We note that the topics on this and past guidance priority lists may be removed or modified based on current priorities. The Agency is not required to publish every guidance on either list if the resources needed would be to the detriment of meeting quantitative review timelines and statutory obligations. In addition, the Agency is not precluded from issuing guidance documents that are not on either list.

FDA and CDRH priorities are subject to change at any time. Topics on this and past guidance priority lists may be removed or modified based on current priorities. CDRH's experience in guidance development has shown that there are many reasons that CDRH staff may not complete the entire agenda of guidances it undertakes. Staff is frequently diverted from guidance development to other priority activities. In addition, at any time new issues may arise to be addressed in guidance that could not have been anticipated at the time the annual list is generated. These may involve newly identified public health issues.

IV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Center for Devices and Radiological Health Guidance Development and Prioritization; Public Workshop; Requests for Comments, available at *http://www.fda.gov/medicaldevices/newsevents/workshopsconferences/ucm394821.htm.*
2. Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices Draft Guidance, available at *http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm433165.pdf.*
3. Radiation Biodosimetry Devices; Draft Guidance for Industry and Food and Drug Administration Staff, available at *http://www.fda.gov/downloads/MedicalDevices/*

DeviceRegulationandGuidance/GuidanceDocuments/UCM427866.pdf.

4. American Glaucoma Society/Food and Drug Administration Workshop on Supporting Innovation for Safe and Effective Minimally Invasive Glaucoma Surgery; Public Workshop, available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm382508.htm.*
5. Regulatory Science Considerations for Medical Countermeasure Radiation Biodosimetry Devices, available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm308079.htm.*
6. Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices, available at *http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm470201.pdf.*

Dated: December 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–32726 Filed 12–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Bioequivalence Recommendations for Paliperidone Palmitate; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry on paliperidone palmitate extended-release injectable suspension entitled ''Draft Guidance on Paliperidone Palmitate.'' The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for paliperidone palmitate extended-release injectable suspension.

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 comments on 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 February 29, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic submissions 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–2007–D–0369 for ''Draft Guidance on Paliperidone Palmitate.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' will be 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.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Xiaoqiu Tang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process