The grant application also expands requirements for partnerships with domestic violence service providers to address the access issues experienced by marginalized victims of domestic violence.

*Respondents:* Recipients of the State Access and Visitation Grant (54 states and territories).

ANNUAL BURDEN ESTIMATES

| Instrument | Total number of respondents | Total number of responses per respondent | Average burden hours per response | Total burden hours | Annual burden hours |
|---|---|---|---|---|---|
| State Access and Visitation Grant Application ..... | 54 | 1 | 10 | 540 | 180 |

*Estimated Total Annual Burden Hours:* 180.

*Authority:* Sec. 469B(e)(3), Pub. L. 104–193.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2022–10832 Filed 5–19–22; 8:45 am]

**BILLING CODE 4184–41–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–N–0517]**

### Medical Devices; 510(k) Sterility Change Master File Pilot Program

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration's (FDA, Agency, or we) Center for Devices and Radiological Health (CDRH or Center) is announcing its 510(k) Sterility Change Master File Pilot Program (''510(k) Sterility Pilot Program''). The 510(k) Sterility Pilot Program is voluntary and intends to give interested companies that terminally sterilize single-use devices (''sterilization providers'') using certain sterilization methods a pathway to submit a Master File for FDA's review. FDA will accept a Master File into the 510(k) Sterility Pilot Program when it determines, among other things, that there is not a likelihood that switching from a fixed chamber ethylene oxide (EtO) sterilization method to the sterilization method described in the Master File could significantly affect the safety or effectiveness of a 510(k)-cleared device that meets the product definition in the Master File and that satisfies other conditions outlined in this document. If a Master File is accepted into the 510(k) Sterility Pilot Program, manufacturers of 510(k)-cleared devices (''510(k) holders'') may choose to reference the Master File in internal documentation in support of a justification for not submitting a new premarket notification (510(k)) under certain conditions as outlined in this document. This voluntary pilot program seeks to encourage industry to consider new, innovative ways to sterilize devices that reduce the potential impact of EtO on the environment and on public health, while ensuring consistent patient access to safe devices and providing a framework for future regulatory approaches that would help address potential device shortages related to EtO sterilization.

**DATES:** FDA is seeking participation in the voluntary 510(k) Sterility Pilot Program beginning May 20, 2022. See the ''Participation'' section for selection criteria for sterilization providers to participate in the 510(k) Sterility Pilot Program and the ''Procedures'' section for instructions on how to submit a Master File for consideration for inclusion into the 510(k) Sterility Pilot Program. Up to nine eligible sterilization providers may be selected for participation in the 510(k) Sterility Pilot Program.

**FOR FURTHER INFORMATION CONTACT:** Clarence W. Murray, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4536, Silver Spring MD 20993, 301–796–0270, *clarence.murray@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

EtO sterilization is an important sterilization method that is widely used to keep devices safe. It is estimated that approximately 50 percent of all sterile devices in the United States are sterilized using EtO (Ref. 1). For many devices, sterilization with EtO may be the only method [1] currently evaluated that effectively sterilizes and does not damage the device during the sterilization process. However, there have been concerns about the effects of EtO exposure and environmental emissions.

In 2019, FDA was made aware of closures of device sterilization facilities due to concerns about the level of EtO emissions (Ref. 2). The Agency closely monitored the situation and worked with device manufacturers affected by the closures to minimize impact to patients who needed device access. Future losses of sterilization capacity due to facility closure have the potential to result in shortages of sterile devices if an alternative for sterilization is not readily available for the devices sterilized at a closed facility. FDA continues to work with manufacturers on site changes, engage with manufacturers about potential solutions to shortage concerns, and collaborate with external stakeholders to help reduce barriers to the utilization of innovative device sterilization technologies. FDA has also taken several actions to advance device sterilization, including sponsoring two innovation challenges to identify alternatives to EtO sterilization methods (Ref. 3) and approaches to reduce EtO emissions (Ref. 4); convening the General Hospital and Personal Use Devices Panel on November 6 and 7, 2019 (''November 2019 Panel Meeting''), to discuss the role of EtO sterilization in maintaining public health (84 FR 46546, September 9, 2019; see also Ref. 5); and announcing an Ethylene Oxide Sterilization Master File Pilot Program (''EtO Pilot Program'') for devices subject to Premarket Application (''PMA'') approval (84 FR 65162, November 26, 2019; see also Ref. 1).

For devices subject to 510(k) requirements, before most sterile devices are cleared for marketing, FDA reviews the submitted 510(k) information to determine, among other considerations, if the provided sterility information is adequate (*e.g.,* in accordance with internationally agreed upon voluntary consensus standards that FDA recognizes). In some cases, if a device manufacturer changes the sterilization method or process for sterilizing the device identified in its original 510(k) submission, the manufacturer may need to submit a new 510(k) for FDA review of these changes and clearance prior to marketing (Ref. 6). However, in addition to public

[1] In this notice, ''method'' generally refers to the type of sterilization and ''processes'' generally refers to steps within that method to achieve a sterile device.

health and environmental concerns regarding EtO emissions, FDA recognizes the need to facilitate timely sterilization method changes to keep device supply chain interruptions at a minimum and to facilitate changes to sterilization processes that utilize reduced EtO concentrations or that utilize other sterilization methods. At the November 2019 Panel Meeting, FDA received feedback from Panel members and stakeholders that the Agency could help prevent device shortages and advance device sterilization by facilitating the development and utilization of safe and effective alternative sterilization methods that 510(k) holders may wish to consider for select sterile devices (Ref. 5).[2]

In general, a change from a fixed chamber EtO sterililzation method to a sterilization method characterized as ''Established Category B'' or ''Novel'' by FDA's guidance, *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile* (Ref. 7), would likely require a new 510(k) because this change could significantly affect the safety or effectiveness of the device (Ref. 6).[3] Under § 807.81(a)(3)) 21 CFR 807.81(a)(3), the submission of a new 510(k) is required prior to a change or modification that could significantly affect the safety or effectiveness of the device, or that is a major change or modification in the intended use of the device. However, FDA also recognizes that for some 510(k)-cleared devices, a change from a fixed chamber EtO sterilization method to an Established Category B or Novel method does not typically significantly affect the safety or effectiveness of the device in certain cases, and therefore may not require submission of a new 510(k) in these cases.

For these reasons, FDA is announcing and soliciting participation in the 510(k) Sterility Pilot Program. Under this pilot program, sterilization providers that sterilize single-use devices using certain sterilization methods characterized as ''Established Category B'' or ''Novel'' may submit a Master File for their sterilization method for FDA review.[4] This review would include consideration of various evaluation and validation methods (described below) that a sterilization provider would ultimately propose to a 510(k) holder interested in implementing a sterilization method other than fixed chamber EtO sterilization. Interested 510(k) holders may use this information in reaching device-specific determinations of whether a change in sterilization method from fixed chamber EtO sterilization to the alternative sterilization method could significantly affect safety or effectiveness of the subject device. For 510(k) holders who are granted a right of reference to an accepted Master File for a particular 510(k)-cleared device under the conditions described below, FDA believes there is a likelihood that switching to the sterilization method described in the Master File could not significantly affect the safety or effectiveness of such device. Accordingly, if a Master File submitted by a 510(k) holder's sterilization provider is accepted by FDA, the 510(k) holder could, under certain conditions and on a voluntary basis, reference the Master File in the 510(k) holder's internal documentation,[5] without submitting a new 510(k) for a sterilization method change from a fixed chamber EtO method to the method described in the Master File. The pilot program is intended to provide expeditious review and feedback to sterilization providers on Master File submissions that may support sterilization changes to 510(k) cleared devices. FDA intends to evaluate pilot participation and the progress of the pilot in 6 months and provide any updates to the pilot in a subsequent notice, if appropriate. At this time, 510(k)s reviewed by the Center for Biologics Evaluation and Research (CBER) and 510(k)s for combination products[6] are outside the scope of this pilot.

For the purposes of this document, the term ''sterilization provider'' is used to refer to a device manufacturer's own in-house sterilization facility or a device manufacturer's contract sterilization provider, and encompasses any subcontractor facilities utilizing the same quality system as the contract sterilization provider, as applicable. This document and the proposed 510(k) Sterility Pilot Program do not otherwise remove or replace applicable statutory or regulatory requirements for EtO-sterilized devices subject to 510(k) submissions.

*A. Participation*

Up to nine sterilization providers may be eligible to participate in this voluntary 510(k) Sterility Pilot Program. The pilot program is limited to sterilization providers that meet the following selection qualities:

1. Be a sterilization provider of a single-use device that is provided sterile;
2. Be in good compliance standing with the Agency; and
3. Submit a Master File in accordance with the procedures set forth in section I.B for a validated sterilization method that may be considered an ''Established Category B'' or ''Novel'' sterilization method as described in FDA's guidance entitled *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile* (Ref. 7).

The following are outside the scope of the 510(k) Sterility Pilot Program and are inappropriate for inclusion in this program:

1. Reusable devices, reprocessed single-use devices, or devices that are provided non-sterile.
2. Combination products.
3. Devices regulated by CBER.
4. Changes to device design, specifications, or materials.
5. Sterilization changes for which there is a likelihood that the change could significantly affect device specifications, device performance, material compatibility, or biocompatibility, or otherwise could significantly affect device safety or effectiveness.[7] [8]

[2] Further, FDA more generally seeks to improve and strengthen the device supply chain through other broader initiatives, such as the planned Resilient Supply Chain and Shortages Prevention Program (RSCSPP). *See* FDA's Budget, Medical Device Supply Chain and Shortages Prevention Program, *https://www.fda.gov/news-events/fda-voices/fdas-budget-medical-device-supply-chain-and-shortages-prevention-program.*

[3] FDA also notes that changes that constitute a major change or modificiation in the intended use of a device would require a new 510(k) submission. § 807.81(a)(3)(ii). Such changes fall outside the scope of this pilot program.

[4] FDA is not including ''Established Category A'' methods within the scope of the pilot program at this time. Manufacturers of 510(k) devices seeking to change from a fixed chamber EtO sterilization method to an ''Established Category A'' method should evaluate the change according to FDA's guidance, ''Deciding When to Submit a 510(k) for a Change to an Existing Device'' in determining whether a new 510(k) is required (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device*). In general, for changes from one ''Established Category A'' method to another ''Established Category A'' method, it is unlikely submission of a new 510(k) is required if the change could not significantly affect the performance or biocompatibility of the device, or constitute a major change or modification in the intended use of the device.

[5] Whenever a manufacturer changes its device, it must take certain actions to comply with the Quality System Regulation (QSR), part 820 (21 CFR part 820), unless a regulatory exemption exists. The QSR requires that design changes and production and process changes be documented prior to implementation. See §§ 820.30(i) and 820.70(b).

[6] See 21 CFR 3.2(e).

[7] Under § 807.81(a)(3), the submission of a new 510(k) is required prior to a change or modification that could significantly affect the safety or effectivess of the device, or that is a major change or modification in the intended use of the device. FDA's guidance entitled ''Deciding When to Submit

6. Sterilization processes used only for intermediate processing prior to final device assembly.

7. Devices with alternate sterility assurance levels (SAL) other than $10^{-6}$.

*B. Procedures*

While the sterilization provider serves as the primary participant of the 510(k) Sterility Pilot Program, FDA anticipates that close collaboration between sterilization providers and 510(k) holders will be necessary to ensure the success of the pilot program. Accordingly, the procedures for sterilization providers and 510(k) holders are set forth below.

1. Procedures for Sterilization Providers

To be considered for the voluntary 510(k) Sterility Pilot Program, a sterilization provider should submit the following information in a Master File for the Agency's review with a cover sheet clearly indicating ''510(k) Sterility Change Master File Pilot Program'' in the subject heading:

1. Name, address, and FDA Establishment Identification (FEI) number of the sterilization facility.

2. Clear identification of all responsibilities of the sterilization facility and device manufacturers with respect to sterilization validation.

3. Information regarding the sterilization method and the operations of the sterilization provider including:

- Methodology for Installation Qualification, Operational Qualification, and Performance Qualification.
- Installation and operational requalification schedule to support continuous process effectiveness.
- Identification and explanation of management structure and involvement for process and facility review.
- Identification and description of a structured program and schedule for independent audits and monitors.
- The sterilization facility's inspectional history and history of compliance with applicable regulations (including, but not limited to, requirements under part 820 (21 CFR part 820).
- Identification and explanation of common potential protocol deviations, along with proposed mitigation of potential deviations. The Master File should also include a strategy to address any deviations that could significantly affect the safety or effectiveness of a device and any deviations not addressed in the Master File.

4. Technical information regarding the sterilization method:

- A description of the sterilization system including system specifications, process parameters and monitors, and a description of the hardware components in the sterilization system.
- An overview of the sterilization cycle(s) and process definition that includes an overview and discussion of the sterilization process and cycle profile(s), as well as a detailed description of the critical parameters, specific exposure conditions for cycles, sterilant, sterilant concentration, and sterilant shelf-life.
- A description of the intended sterilization load and product definition that includes defining the critical load characteristics and ranges, and describes the procedure used to determine if a device meets the product definition.
- Generally applicable microbiological testing information and the validation methodology and results used to demonstrate that the process can achieve an SAL of $10^{-6}$ when carried out on a device. This information should support that the test microorganism(s) used to validate and monitor the sterilization cycle is the most resistant microorganism(s) and provide resistance characteristics for the most resistant microorganism(s). This testing may include sporicidal testing, D-value determination based upon survivor curve analysis and fraction negative analysis, half cycle testing, total kill endpoint testing, and external process challenge device (ePCD) and internal process challenge device (iPCD) lethality testing. The generalized sterilization method development and validation information provided in the proposed Master File should be consistent with ANSI/AAMI/ISO 14937:2009/(R)2013, *Sterilization of health care products—General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices.*
- A summary of how the biological performance testing is used to define process parameters, and a summary of physical tests which demonstrate that the sterilizer achieves and maintains the required physical/chemical process lethality conditions within specifications. These data should be from repeated runs with varying load conditions (*e.g.,* minimum and maximum loading configurations).
- A description of the validated biological and/or chemical indicators used with the sterilization method and how the indicators are used to monitor sterilization cycles. Describe the types of packaging used with the validated cycles in order to maintain sterility.
- Identification of compatible/incompatible materials and describe how material compatibility is assessed for devices sterilized with the method.
- A description of how biocompatibility is assessed for devices that are switched to the method to ensure that biocompatibility is not significantly affected, and an assessment of toxicity for the sterilant and any common byproducts. Describe how removal or dissipation of the sterilant and byproducts is achieved.
- Identification of all relevant consensus standards used and any aspects of the standards that were not met. Deviations should be identified, addressed and justified or mitigated, as applicable.
- If leveraging or referencing previous interactions with FDA (*e.g.,* Innovation Challenge discussions, Q-Submissions, etc.) in the Master File, provide the submission number as a reference.

For more information on Master Files, see FDA's website: *https://www.fda.gov/medical-devices/premarket-approval-pma/master-files.*

Following receipt of a Master File containing the information described in section I.B.1 of this document, FDA will determine eligibility for the pilot program by evaluating whether the criteria outlined in Sections I.A and I.B.1 of this document have been met, and provide written feedback that FDA either accepts the Master File into the 510(k) Sterility Pilot Program or has determined that the Master File is outside the scope of the pilot program. FDA intends to work interactively with the Master File holder to address any deficiencies with the information provided in the Master File. If a Master File is outside the scope of the pilot program, the written feedback will identify the reasons the Master File was determined to be out of scope.

If accepted into the pilot program, the Master File holder should submit amendments to FDA every 6 months with information on any process changes, a list of devices for which the sterilization method has been changed from fixed chamber EtO sterilization to the sterilization method described in the

a 510(k) for a Change to an Existing Device'' discusses specific factors to consider when assessing if a change to a 510(k) cleared device, including a sterilization change, may require a new 510(k) pursuant to § 807.81. This guidance is available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device.*

[8] The responsibility for determining whether a change from EtO sterilization to the sterilization method described in a Master File could significantly affect the safety or effectiveness of a particular 510(k)-cleared device continues to rest with the 510(k) holder. FDA's acceptance of a Master File into the 510(k) Sterility Pilot Program should not be understood to supplant a 510(k) holder's obligation to conduct a device-specific evaluation of whether the change described in the Master File could significantly affect the safety or effectiveness of a device in a particular case.

Master File and for which a right of reference to the Master File has been granted (except devices which have already been identified in a prior amendment), and any other changes to the information contained in the Master File, to maintain participation in the pilot program. If there have been no updates or changes, the Master File holder should notify FDA of the absence of any updates or changes in lieu of submitting an amendment. The description included in the amendments of devices for which the sterilization method has been changed from fixed chamber EtO sterilization to the sterilization method described in the Master File, and for which a right of reference to the Master File has been granted, should include:

1. The manufacturer(s) of the device(s);
2. Each device name;
3. The 510(k) number(s) for the device(s); and
4. A description of how each device added to the Master File meets the product definition in the accepted Master File.

This information may be used to inform FDA's understanding of how the product definition is being interpreted and applied in practice. Following receipt of an amendment, FDA will evaluate whether the Master File, as amended, remains within the scope of the pilot program, and will notify the Master File holder that FDA either accepts the amendment, or has determined that the amendment, in whole or in part, would cause the Master File to be outside the scope of the pilot program.

If a sterilization provider is accepted into the pilot program and does not maintain participation (*e.g.,* through non-submission of amendments, updates, or other information requested by FDA under the pilot program) or no longer wishes to participate in the pilot program, the sterilization provider should notify 510(k) holders for whom they granted a right of reference to the Master File. If the Master File holder does not maintain participation in the pilot program, FDA may determine that the Master File for that sterilization process is outside the scope of the pilot program.

2. Procedures for 510(k) Holders

510(k) holders who wish to change their sterilization method for a previously cleared device from a fixed chamber EtO sterilization method to the sterilization method described in a Master File that has been accepted into the pilot program should use the following procedures. Once a sterilization provider has proposed, and FDA has accepted, a Master File into the pilot program, interested 510(k) holders may choose to review the information in the Master File in carrying out device-specific analyses of whether the alternative sterilization method could significantly affect safety or effectiveness. If the 510(k) holder has determined that the alternative sterilization method could not significantly affect safety or effectiveness of the subject device, and if the 510(k) holder has a right of reference to the Master File granted by the Master File holder, the 510(k) holder may reference the Master File in internal documentation supporting the change from a fixed chamber EtO sterilization method to the method described in the referenced Master File. The internal documentation supporting the change should include:

1. Name, address, and FEI number of the sterilization facility.
2. Master File number in which the referenced sterilization procedures are described, with signed right of reference from the Master File holder identifying the devices to be sterilized under the Master File.
3. List of device(s) to be sterilized (identified by manufacturer, trade name, model number, and 510(k) number).
4. A summary of the information used to support the conclusion of the 510(k) holder that the method described in the Master File achieves an SAL of $10^{-6}$ for the subject device and that the sterilization method could not significantly affect the device's design, specifications, performance, or biocompatibility, or otherwise could not significantly affect device safety or effectiveness.

This Pilot Program does not otherwise remove or replace any requirements, such as, but not limited to, recordkeeping requirements under part 820, premarket notification requirements under part 807 (21 CFR part 807), subpart E, and labeling requirements under 21 CFR part 801. It is the manufacturer's responsibility to ensure compliance with applicable laws and regulations.

During this voluntary 510(k) Sterility Pilot Program, CDRH staff intends to be available to answer questions or concerns that may arise. The 510(k) Sterility Pilot Program participants may comment on and discuss their experiences with the Center.

## II. Paperwork Reduction Act of 1995

This notice 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 part 820, regarding the Quality System regulations, have been approved under OMB control number 0910–0073. The collections of information in part 807, subpart E, regarding premarket notification submission, have been approved under OMB control number 0910–0120.

## III. References

The following references are on display in the Dockets Management Staff (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 *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. U.S. Food and Drug Administration, ''Ethylene Oxide Sterilization for Medical Devices,'' available at: *https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices.*
2. U.S. Food and Drug Administration, ''Statement on Concerns With Medical Device Availability Due to Certain Sterilization Facility Closures,'' available at: *https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures.*
3. U.S. Food and Drug Administration, ''FDA Innovation Challenge 1: Identify New Sterilization Methods and Technologies,'' available at: *https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-1-identify-new-sterilization-methods-and-technologies.*
4. U.S. Food and Drug Administration, ''FDA Innovation Challenge 2: Reduce Ethylene Oxide Emissions,'' available at: *https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-2-reduce-ethylene-oxide-emissions.*
5. U.S. Food and Drug Administration, ''November 6 and 7, 2019: General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee Meeting Announcement,'' available at: *https://www.fda.gov/advisory-committees/advisory-committee-calendar/november-6-7-2019-general-hospital-and-personal-use-devices-panel-medical-devices-advisory-committee.*
6. U.S. Food and Drug Administration, ''Deciding When to Submit a 510(k) for a Change to an Existing Device,'' available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device.*

7. U.S. Food and Drug Administration, ''Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile,'' available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled.*

Dated: May 13, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–10925 Filed 5–19–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2007–D–0369]**

### Product-Specific Guidances; Draft and Revised Draft Guidances 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 additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The guidances identified in this notice were developed using the process described in that guidance.

**DATES:** Submit either electronic or written comments on the draft guidance by July 19, 2022 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:

- *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–2007–D–0369 for ''Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.'' 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 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:** Christine Le, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993–0002, 301–796–2398, *PSG-Questions@fda.hhs.gov.*

**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'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

As described in that guidance, FDA adopted this process as a means to