January 25, 2023 (88 FR 4797). Submit either electronic or written comments on the draft guidance by May 8, 2023, to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance.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include the Docket No. FDA–2022–D–0278 for ''Action Levels for Lead in Food Intended for Babies and Young Children; Draft Guidance for Industry.''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.'' We will review this copy, including the claimed confidential information, in our 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.

FOR FURTHER INFORMATION CONTACT: Eileen Abt, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1700; or Philip Chao, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of January 25, 2023 (88 FR 4797), we published a notice of availability for a draft guidance entitled ''Action Levels for Lead in Food Intended for Babies and Young Children; Draft Guidance for Industry.'' This action opened a docket with a 60-day comment period to receive comments related to action levels for lead in processed food intended for babies and young children.

We have received a request for a 60-day extension of the comment period for the draft guidance to provide additional time to provide analytical data. In the interest of balancing the public health importance of establishing action levels for lead in food labeled for babies and young and granting additional time to submit comments before we finalize the draft guidance, we have concluded that it is reasonable to reopen the comment period for 30 days, until May 8, 2023. We are reopening the comment period because the request for an extension of the comment period arrived too late for us to extend the comment period. We believe that an additional 30 days allows adequate time for interested persons to submit comments.

Dated: April 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07187 Filed 4–5–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1057]

Notification of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Notification of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act.'' The draft guidance is intended to assist applicants and manufacturers in providing FDA timely, informative notifications about changes in the production of certain finished drugs and biological products as well as certain active pharmaceutical ingredients (API) that may, in turn, help the Agency in its efforts to prevent or mitigate shortages. The draft guidance also explains how FDA communicates information about products in shortage to the public. This

draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by June 5, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by June 5, 2023.

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–2020–D–1057 for ''Notification of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act.'' 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 this 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; or to Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Jin Ahn, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6234, Silver Spring, MD 20993–0002, 301–796–1300; or Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

With regard to the proposed collection of information: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Notification of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act.'' The draft guidance discusses section 506C of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356c), as amended by the Coronavirus Aid, Relief, and Economic Security (CARES) Act,[1] and FDA's regulations which generally require certain applicants and manufacturers to notify FDA of: (1) a permanent discontinuance in the manufacture of certain products, (2) an interruption in the manufacture of certain products that is likely to lead to a meaningful disruption in supply of those products in the United States, (3) a permanent discontinuance in the manufacture of API for certain products, or (4) an interruption in the manufacture of API for certain products that is likely to lead to a meaningful disruption in the supply of the API for those products. The draft guidance, when finalized, would recommend that applicants and manufacturers provide additional details and follow additional procedures to ensure FDA has the

[1] The CARES Act (Pub. L. 116–136) was enacted on March 27, 2020. The CARES Act amendments to section 506C of the FD&C Act took effect on September 23, 2020. See section 3112(g) of the CARES Act.

specific information it needs to help prevent or mitigate shortages. The draft guidance also explains how FDA communicates information about products in shortage to the public.

While some supply disruptions and product shortages cannot be predicted or prevented, early communication and detailed notifications from manufacturers to the Agency play a significant role in decreasing the incidence, impact, and duration of supply disruptions and product shortages. Timely notifications that include specific information about the situation allow the Agency to evaluate the situation and determine an appropriate course of action. When FDA does not receive timely, informative notifications, the Agency's ability to respond appropriately is limited. Therefore, FDA is issuing this guidance to assist applicants and manufacturers in providing FDA timely, informative notifications about changes in the production of certain finished drugs and biological products as well as certain API that may, in turn, help the Agency in its efforts to prevent and mitigate shortages. Among other things, the draft guidance, when finalized, would explain: (1) who must notify FDA and what products are subject to the notification requirements, (2) when to notify FDA, and (3) what details to include in notifications that will ensure FDA has information that would be helpful to assess the potential for a supply disruption or shortage.

When finalized, this guidance will replace the March 2020 guidance entitled ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act.''

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 notifying FDA of a discontinuance or interruption in manufacturing of finished products or API under section 506C of the FD&C Act. 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. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). Under the PRA, Federal Agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information in §§ 310.306, 314.81, and 600.82 (21 CFR 310.306, 314.81(b)(3)(iii), and 600.82) have been approved under OMB control number 0910–0001. The draft guidance describes the requirements in these regulations for applicants or manufacturers of certain drugs and biological products to notify FDA of a permanent discontinuance in the manufacture of certain finished products or an interruption in manufacture of certain finished products that is likely to lead to a meaningful disruption in the supply of such products in the United States.

In addition, the draft guidance refers to notification requirements added to section 506C of the FD&C Act by the CARES Act and, when finalized, would describe additional recommendations for the submission of information that have not been previously approved by OMB under the PRA.

Section III.B of the draft guidance refers to requirements for when notifications must be submitted to FDA under section 506C of the FD&C Act and FDA regulations, but also requests that manufacturers submit notifications to FDA in specific circumstances when notification is not required. For example, if a manufacturer is considering taking an action that may lead to a meaningful disruption in the supply of a product (*e.g.,* holding production to investigate a quality issue or transfer of ownership), the draft guidance requests that the manufacturer notify FDA immediately. The draft guidance also requests that manufacturers notify FDA when they are unable to meet demand for certain products covered by the notification requirement under section 506C of the FD&C Act, even in the absence of an interruption in manufacturing, for example, when there is a sudden, unexpected spike in demand.

Section III.C of the draft guidance refers to requirements for information that must be included in notifications under section 506C(a) of the FD&C Act concerning permanent discontinuances or interruptions in manufacturing of covered finished products, but also recommends that additional information be included in such notifications. For example, the draft guidance states that under section 506C(a) of the FD&C Act notifications must include:

- If an API is a reason for, or risk factor in, the discontinuation or interruption in manufacturing of a covered finished product, the source of the API and any alternative sources for the API known by the manufacturer and
- Whether any associated device used for preparation or administration included in the product is a reason for, or risk factor in, the discontinuation or interruption in manufacturing of the covered finished product.

In addition, the draft guidance recommends that notifications provide certain additional information beyond what is required under section 506C of the FD&C Act and FDA's regulations. The following are examples of additional information that FDA recommends be included in notifications of a permanent discontinuance or interruption in manufacturing concerning a covered finished product:

- The anticipated time frame for all existing product (on hand and in distribution channels) to be exhausted if the notification is for a permanent discontinuance;
- The estimated market share for the product and whether the entire market share is affected by this issue;
- Amount of current inventory of product at the manufacturing facility or warehouse; and
- Whether a proposal is available for FDA to review to expedite availability of

the product or suggestions for FDA actions that may help prevent or mitigate a supply disruption or shortage.

Section III.D of the draft guidance describes what information to include in notifications about permanent discontinuances or interruptions in manufacturing of API for covered finished products. Similar to section III.C, the draft guidance in section III.D refers to requirements for what information must be included in notifications under section 506C(a) of the FD&C Act concerning permanent discontinuances or interruptions in manufacturing of APIs for covered finished products but also recommends that additional information be included in such notifications.

Based on FDA's extensive experience receiving notifications required under §§ 310.306, 314.81(b)(3)(iii), and 600.82 and working closely with manufacturers to prevent and mitigate shortages, we estimate that 10 percent of the 75 respondents currently covered by OMB control number 0910–0001 [2] (''number of respondents'' in table 1, row 1) will submit 1 additional notification concerning covered finished products annually (''number of responses per respondent'' in table 1, row 1) for certain circumstances that are not required by section 506C of the FD&C Act and FDA regulations, such as an inability to meet demand even with no interruption in manufacturing. This would lead to an additional 7.5 responses annually (''total annual responses'' in table 1, row 1). We estimate that each new response will take approximately 2.75 hours to prepare (2 hours per response as currently approved in OMB control number 0910–0001 and an additional 0.75 hours, as described below) (''hours per response'' in table 1, row 1).

Also based on our experience receiving notifications and working closely with manufacturers to prevent and mitigate shortages, we estimate that the new information that the CARES Act amended section 506C of the FD&C Act to require in notifications, as well as information that FDA recommends in the draft guidance that respondents provide beyond what is required under section 506C would lead to respondents spending an additional 0.75 hours per response (''hours per response'' in table 1, row 2). We anticipate that the additional 0.75 hours will provide sufficient time for respondents to gather and compile the required and voluntary information for submission to FDA. Currently, under OMB control number 0910–0001, it is estimated that FDA receives 352.5 responses annually, and the additional 0.75 hours would apply to each response.

For the new category of notifications required regarding discontinuances and interruptions in manufacturing of API of covered finished products, the respondents remain the same as those currently covered by OMB control number 0910–0001 (subject to the requirements in §§ 310.306, 314.81(b)(3)(iii), and 600.82). However, based on our understanding of the frequency of API manufacturing issues and disruptions in API supply, we anticipate that 50 percent of the 75 respondents currently covered by OMB control number 0910–0001 (''number of respondents'' in table 1, row 3) will submit 1 notification related to API annually. This would lead to 37.5 responses annually (''total annual responses'' in table 1, row 3). In light of anticipated coordination between the applicant or finished product manufacturer and the API supplier, we estimate a burden of 2 hours per response.

FDA estimates the additional burden of this collection of information as follows:

Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products OMB Control Number 0910–0001—Revision

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance on notification of a permanent discontinuance or interruption in manufacturing under section 506C of the FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Voluntary Notifications of Circumstances Where Supply May Not Meet Demand for Finished Products (described in section III.B)	75	0.1	7.5	2.75	20.63
Additional Information on the Discontinuance or Interruption in Manufacturing of Finished Products (described in section III.C)	75	4.7	352.5	0.75	264.38
Notifications Regarding Discontinuances and Interruptions in Manufacturing of API	75	0.5	37.5	2	75
Total					360

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

[2] The respondents are applicants of approved new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologic license applications (BLAs), as well as manufacturers of prescription drugs marketed without an approved ANDA or NDA if the product is life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, including use in emergency medical care or during surgery, and is not a radiopharmaceutical product. BLA applicants of blood or blood components are respondents if they manufacture a significant percentage of the nation's Blood supply. We note that the CARES Act clarified that products that are ''intended for use in the prevention or treatment of a debilitating disease or condition'' includes ''any . . . [product] that is critical to the public health during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act.'' This clarification does not affect the estimated number of respondents because it does not change the products or manufacturers covered by the notification requirement; it merely clarifies that manufacturers of products critical to the public health during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act are covered.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07238 Filed 4–5–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–0026]

Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments Into Endpoints for Regulatory Decision-Making; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; 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 a draft guidance for industry entitled ''Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments Into Endpoints for Regulatory Decision-Making.'' This draft guidance (Guidance 4) is the fourth in a series of four methodological patient-focused drug development (PFDD) guidance documents that describe how stakeholders (patients, researchers, medical product developers, and others) can collect and submit patient experience data and other relevant information from patients and caregivers to be used for medical product development and regulatory decision-making.

DATES: Submit either electronic or written comments on the draft guidance by July 5, 2023 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–2023–D–0026 for ''Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments Into Endpoints for Regulatory Decision-Making.'' 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: Shannon Sparklin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6306, Silver Spring, MD 20993–0002, 301–796–9208, *Shannon.Sparklin@fda.hhs.gov;* or Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Office of Strategic