ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
ORR–9 (Annual Survey of Refugees)	6000	2000	1	0.5	1000
Pre-survey information form	6000	2000	1	0.05	100

Estimated Total Annual Burden Hours: 1,100.

Authority: Sec. 413.[8 U.S.C. 1523].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2018–27235 Filed 12–14–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3454]

Manufacturing Site Change Supplements: Content and Submission; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Manufacturing Site Change Supplements: Content and Submissions; Guidance for Industry and Food and Drug Administration Staff.'' This guidance describes the decision-making steps that FDA recommends to determine whether a premarket approval application (PMA) supplement should be submitted when a manufacturer intends to change the manufacturing site (including a change to the processing, packaging, or sterilization site) of its legally marketed PMA-approved device. This guidance also discusses the general factors FDA intends to consider when determining whether to conduct an establishment inspection prior to approval of a site change supplement.

DATES: The announcement of the guidance is published in the **Federal Register** on December 17, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2015–N–3454 for ''Manufacturing Site Change Supplements: Content and Submission; Guidance for Industry and Food and Drug Administration Staff.'' 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.

- 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.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Manufacturing Site

Change Supplements: Content and Submissions: Guidance for Industry and Food and Drug Administration Staff'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or the 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.

FOR FURTHER INFORMATION CONTACT: Bleta Vuniqi, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3463, Silver Spring, MD 20993–0002, 301–796–5497.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 515(d)(6) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360e(d)(6)), a PMA supplement must be submitted for review and approval by FDA before making a change that affects the device's safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacture, which would be eligible for a 30-day notice. The PMA regulations provide general criteria in 21 CFR 814.39 for determining when PMA holders are required to submit a PMA supplement or are eligible to submit a 30-day notice.

This guidance document explains: (1) What constitutes a manufacturing site change and when a manufacturer should submit a PMA supplement for a site change; (2) what documentation a manufacturer should submit in the site change supplement; and (3) the general factors that FDA intends to consider when determining whether to conduct an establishment inspection prior to the approval of a site change supplement. This guidance is intended to help industry decide when a change in manufacturing site should be submitted in a PMA site change supplement. This guidance is also intended to help industry predict when a preapproval inspection in connection with a PMA supplement for a manufacturing site change will likely be needed to evaluate the firm's implementation of Quality System regulation requirements, 21 CFR part 820. As a result, this guidance should help manufacturers manage the timeframes associated with implementing the changes in the manufacturing site and any processes, methods, procedures, qualifications, and validations.

Please note that this guidance only applies to a manufacturer of a device with an approved PMA, a product development protocol, or a humanitarian device exemption. This guidance does not address manufacturing site changes for devices cleared under the premarket notification (510(k)) submissions, granted premarket authorization through the De Novo pathway, or approved and distributed as part of an investigational device exemption.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of October 21, 2015. FDA revised the guidance as appropriate in response to the comments.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Manufacturing Site Change Supplements: Content and Submission; Guidance for Industry and Food and Drug Administration Staff.'' 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. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Manufacturing Site Change Supplements: Content and Submissions; Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1269 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. 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 the following FDA regulations or guidance have been approved by OMB as listed in the following table.

21 CFR part or guidance	Topic	OMB control No.
814, subparts A through E	Premarket Approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-Submissions	0910–0756
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
807, subparts A through D	Electronic Submission of Medical Device Registration and Listing.	0910–0625

Dated: December 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–27237 Filed 12–14–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4115]

Clarification of Radiation Control Regulations for Manufacturers of Diagnostic X-Ray Equipment; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Clarification of Radiation Control Regulations for Manufacturers of Diagnostic X-Ray Equipment.'' This draft guidance provides clarification to industry and FDA staff of the Federal regulations that relate to diagnostic x-ray systems and their major components. These regulations pertain to the recordkeeping, reporting, manufacturing, importing, and installation of ''electronic products,'' as defined in FDA regulations. This draft guidance, when finalized, will supersede FDA's guidance entitled ''Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment.'' 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 February 15, 2019 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–2018–D–4115 for ''Clarification of Radiation Control Regulations for Manufacturers of Diagnostic X-Ray Equipment.'' 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.

- 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.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Clarification of Radiation Control Regulations for Manufacturers of Diagnostic X-Ray Equipment'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Scott Gonzalez, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4276, Silver Spring, MD 20993–0002, 301–796–5889.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance provides clarification to industry and FDA staff of the Federal regulations that relate to diagnostic x-ray systems and their major components. The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines diagnostic x-ray systems as both a medical device, under section 201(h) of the FD&C Act (21 U.S.C. 321(h)), and an electronic product, under section 531 of the FD&C Act (21 U.S.C. 360hh). As such, these devices are subject to the provisions of the FD&C Act that apply to medical devices (*e.g.,* sections 510