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

Type of respondent	Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total annual hours
LGBT young adults aged 18–24 in the select media markets—Recruited via social media (30% combined eligibility and response rate).	Screener—First media tracking.	556	1	556	0.083	46
	Screener—Second media tracking.	556	1	556	0.083	46
	Screener—Third media tracking.	556	1	556	0.083	46
Media tracking screeners	.....	1,668	.....	1,668	.....	138
LGBT young adults aged 18–24 in the select media markets—Recruited via social media (30% combined eligibility and response rate).	Questionnaire—First media tracking.	167		167	0.667	111
	Questionnaire—Second media tracking.	167	1	167	0.667	111
	Questionnaire—Third media tracking.	167	1	167	0.667	111
Media tracking questionnaires.	.....	501	.....	501	.....	333
Total media tracking (screeners and questionnaires).	.....	2,169	.....	2,169	.....	471
Totals Across All Study Components.	.....	15,288	.....	15,288	.....	3,839

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

Dated: October 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–26671 Filed 10–20–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3454]

Manufacturing Site Change Supplements: Content and Submission; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Manufacturing Site Change Supplements: Content and Submission''. This draft guidance describes the decision-making steps that FDA recommends to determine whether a premarket approval application (PMA) supplement should be submitted when a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 to determine whether a preapproval inspection is necessary before approval of the PMA supplement. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 19, 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–3454 for ''Manufacturing Site Change Supplements: Content and Submission.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Manufacturing Site Change Supplements: Content and Submission'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), 10903 New Hampshire Ave., Bldg. 71, Rm. 3103, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149.

FOR FURTHER INFORMATION CONTACT: William MacFarland, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002, 301–796–5547; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 515(d)(6) of the Federal Food, Drug, and Cosmetic Act (the FD&C 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 § 814. 39 (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. Pursuant to § 814.39(a)(3), a PMA holder must submit a PMA supplement for review and approval by FDA concerning the ''use of a different facility or establishment to manufacture, process, or package the device'' that affects the safety or effectiveness of a device before implementing the change. With respect to establishment inspections, section 510(h) of the FD&C Act (21 U.S.C. 360(h)) requires every registered establishment to be subject to inspections pursuant to section 704 of the FD&C Act (21 U.S.C. 374) and to be inspected at least once in the 2-year period after registration and at least once in every successive 2-year period thereafter.

In March 1996, CDRH sent a letter to the medical device industry that announced a 1-year pilot program to improve the processing of PMA supplements for changes in manufacturing sites. The letter discussed the need to improve the speed and efficiency of CDRH review and approval of manufacturing site change supplements, and stated that CDRH did not require preapproval inspection for all site changes. CDRH later developed the draft guidance entitled ''Likelihood of Facilities Inspections When Modifying Devices Subject to Premarket Approval,'' which was issued on August 5, 1999. This guidance was never finalized.

The PMA supplements described in the March 1996 letter and the 1999 draft guidance were called ''site change supplements'' or, if no preapproval inspection was required, they were termed ''express supplements.'' FDA now identifies all such submissions as ''site change supplements'' with a designation of whether or not an inspection is needed before the change can be implemented. Based on feedback from industry and the Agency's experience over many years, FDA has made substantial revisions and updates to the 1999 draft guidance and is reissuing it for comment as this Level 1 draft guidance.

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 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. The 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 premarket notification (510(k)) submissions.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on manufacturing site change supplements' content and submission. 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.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov* or from CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''Manufacturing Site Change Supplements: Content and Submission'' 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 draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814, subparts B and E have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

Dated: October 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–26637 Filed 10–20–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2029]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Administrative Practices and Procedures; Formal Evidentiary Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Administrative Practices and Procedures; Formal Evidentiary Public Hearing'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On May 12, 2015, the Agency submitted a proposed collection of information entitled ''Administrative Practices and Procedures; Formal Evidentiary Public Hearing'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0191. The approval expires on September 30, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: October 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–26639 Filed 10–20–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0893]

Agency Information Collection Activities; Proposed Collection; Comment Request; Center for Devices and Radiological Health Appeals Processes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with the processes available to outside stakeholders to request additional review of decisions or actions by Center for Devices and Radiological Health (CDRH) employees.

DATES: Submit either electronic or written comments on the collection of information by December 21, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. [FDA–2011–D–0893] for Agency Information