device experience reporting is approved under OMB control number 0910–0471 through May 31, 2017; investigational new drug application regulations are approved under OMB control number 0910–0014 through December 31, 2015; and investigational device exemption reporting is approved under OMB control number 0910–0078 through March 31, 2016). Any additional burden imposed by this proposed collection would be minimal.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests to Issue an EUA or a Substantive Amendment to an Existing EUA	6	3	18	45	810
FDA Review of a Pre-EUA Package or an Amendment Thereto	13	6	78	34	2,652
Manufacturers of an Unapproved EUA Product	5	2	10	2	20
Public Health Authorities; Unapproved EUA Product	30	3	90	2	180
Total					3,662

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of respondent	No. of recordkeepers	No. of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Manufacturers of an Unapproved EUA Product	5	2	10	25	250
Public Health Authorities; Unapproved EUA Product	30	3	90	3	270
Total					520

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

Dated: *December 17, 2015.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–32253 Filed 12–22–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4644]

Draft Guidance for Industry on Advancement of Emerging Technology Applications To Modernize the Pharmaceutical Manufacturing Base; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Advancement of Emerging Technology Applications to Modernize the Pharmaceutical Manufacturing Base.'' This guidance provides recommendations to pharmaceutical companies interested in participating in a program involving the submission of chemistry, manufacturing, and controls (CMC) information containing emerging manufacturing technology. The program is open to companies that intend the technology to be submitted as part of an investigational new drug application (IND), or an original or supplemental new drug application (NDA), abbreviated new drug application (ANDA), or biologics license application (BLA) reviewed by the Center for Drug Evaluation and Research (CDER), where that technology meets certain criteria described in the guidance.

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 on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 22, 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–D–4644 for ''Advancement of Emerging Technology Applications to Modernize the Pharmaceutical Manufacturing Base.'' 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.

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: Sau L. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4144, Silver Spring, MD 20993–0002, 301–796–2905; or for further information or to submit requests to participate in the program, please use *CDER–ETT@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Advancement of Emerging Technology Applications to Modernize the Pharmaceutical Manufacturing Base.'' The Office of Pharmaceutical Quality and Office of Compliance, CDER, are committed to supporting and enabling the modernization of pharmaceutical manufacturing as part of the Agency's mission to protect and promote the public health. While the implementation of emerging technology is critical to modernizing pharmaceutical manufacturing and improving quality, FDA also recognizes that innovative approaches to manufacturing may represent challenges to industry and regulators. By the very nature of an approach being innovative, a limited knowledge and experiential base about the technology may exist. Pharmaceutical companies may have concerns that using such technologies could result in delays while FDA reviewers familiarize themselves with the new technologies and determine how they fit within existing regulatory approaches. Through CDER's Emerging Technology Team, FDA intends to encourage the adoption of innovative approaches to pharmaceutical manufacturing by leveraging existing resources within the Agency to facilitate the regulatory review of submissions to the Agency involving manufacturing technologies likely to improve product safety, identity, strength, quality, and purity.

The draft guidance provides recommendations to pharmaceutical companies interested in participating in a program involving the submission of CMC information containing emerging manufacturing technology to FDA. Acceptance of a request to participate in this CDER program will depend on the applicant's proposed plan for submission of an IND or original or supplemental ANDA, BLA, or NDA, based on certain criteria described in the guidance. To be considered for inclusion in the program, the proposal should be for an innovative or novel product, manufacturing process, and/or testing technology that is subject to CMC review, and for which the Agency has limited review or inspection experience.

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 Advancement of Emerging Technology Applications to Modernize the Pharmaceutical Manufacturing Base. 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. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that 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 information to be included in a meeting request for a product submitted in an IND, BLA, or NDA is approved under OMB control number 0910–0429 (Guidance for Industry on Formal Meetings Between the FDA and Sponsors or Applicants). Information to be included in a meeting request for a product submitted in an ANDA is approved under OMB control number 0910–0797 (Guidance on Controlled Correspondence Related to Generic Drug Development). The submission of INDs under 21 CFR 312.23 is approved under OMB control number 0910–0014; the submission of BLAs under 21 CFR 601.2 and 601.12 is approved under OMB control number 0910–0338; and the submission of NDAs and ANDAs under 21 CFR 314.50, 314.70, 314.71, 314.94, and 314.97 are approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: December 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–32316 Filed 12–22–15; 8:45 am]

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