Federal Register notice must use the appropriate FDA-supported standards, formats, and terminologies specified in the Data Standards Catalog for NDA, ANDA, and certain BLA submissions. Study data contained in certain IND submissions must use the specified formats for electronic submission in studies with a start date 36 months or later after this **Federal Register** notice of availability.

In section 745A(a) of the FD&C Act, Congress granted explicit authorization to FDA to implement the statutory electronic submission requirements by specifying the format for such submissions in guidance. Because this guidance provides such requirements under section 745A(a) of the FD&C Act, indicated by the use of the words must or required, it is not subject to the usual restrictions in FDA's good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities. See 21 CFR 10.115(d).

II. Paperwork Reduction Act of 1995

The 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 guidance pertains to sponsors and applicants making regulatory submissions to FDA in electronic format for NDAs, ANDAs, BLAs, and INDs. The information collection discussed in the guidance is contained in our IND regulations (21 CFR part 312) and approved under OMB control number 0910–0014, our NDA regulations (including ANDAs) (21 CFR part 314) and approved under OMB control number 0910–0001, and our BLA regulations (21 CFR part 601) and approved under OMB control number 0910–0338.

Sponsors and applicants have been voluntarily submitting standardized study data in electronic format. Under FDASIA, sponsors and applicants will be required to make all of these submissions electronically in compliance with the specified standards, formats, and terminologies. These requirements will be phased in over 2- and 3-year periods after the issuance of this guidance.

For many years sponsors and applicants have been submitting electronically using the electronic common technical document format and have included electronic study data in both legacy and standardized formats. For some sponsors and applicants there may be new costs, including capital costs or operating and maintenance costs, which would result from the requirements under FDASIA and this guidance, because some sponsors and applicants would have to change from submissions that have included legacy (non-standard) study data to submissions in compliance with this guidance. FDA estimates that for some sponsors and applicants the costs may be as follows:

- *Data management (hardware/software):* $350,000–$1,000,000
- *Initial data management operations:* $500,000–$1,000,000
- *Training:* $100,000—$250,000

III. Comments

Interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

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

Dated: December 12, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29608 Filed 12–17–14; 8:45 am]

BILLING CODE 4164–01–P

approved (signed) by the Study Director. For example, see Study Start Date in the SEND Trial Summary Domain (TSPARMCD = STSTDTC), *http://www.cdisc.org.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0085]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 20, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0629. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics—(OMB Control Number 0910–0629)—Extension

The guidance document provides information concerning cooperative manufacturing arrangements applicable to biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262). The guidance addresses several types of manufacturing arrangements (*i.e.,* short supply arrangements, divided manufacturing arrangements, shared manufacturing arrangements, and contract manufacturing arrangements) and describes certain reporting and recordkeeping responsibilities, associated with these arrangements, including the following: (1) Notification of all important proposed changes to production and facilities; (2) notification of results of tests and investigations regarding or possibly impacting the product; (3) notification of products manufactured in a contract facility; and (4) standard operating procedures.

1. Notification of All Important Proposed Changes to Production and Facilities

Each licensed manufacturer in a divided manufacturing arrangement or shared manufacturing arrangement must notify the appropriate FDA Center regarding proposed changes in the manufacture, testing, or specifications of its product, in accordance with § 601.12 (21 CFR 601.12). In the guidance, we recommend that each licensed manufacturer that proposes such a change should also inform other participating licensed manufacturer(s) of the proposed change.

For contract manufacturing arrangements, we recommend that the contract manufacturer should share with the license manufacturer all important proposed changes to production and facilities (including introduction of new products or at inspection). The license holder is responsible for reporting these changes to FDA (§ 601.12).

2. Notification of Results of Tests and Investigations Regarding or Possibly Impacting the Product

In the guidance, we recommend the following for contract manufacturing arrangements:

- The contract manufacturer should fully inform the license manufacturer of the results of all tests and investigations regarding or possibly having an impact on the product; and
- The license manufacturer should obtain assurance from the contractor that any FDA list of inspectional observations will be shared with the license manufacturer to allow evaluation of its impact on the purity, potency, and safety of the license manufacturer's product.

3. Notification of Products Manufactured in a Contract Facility

In the guidance, we recommend for contract manufacturing arrangements that a license manufacturer cross reference a contract manufacturing facility's Master Files only in circumstances involving certain proprietary information of the contract manufacturer, such as a list of all products manufactured in a contract facility. In this situation, the license manufacturer should be kept informed of the types or categories of all products manufactured in the contract facility.

4. Standard Operating Procedures

In the guidance, we remind the license manufacture that the license manufacturer assumes responsibility for compliance with the applicable product and establishment standards (21 CFR 600.3(t)). Therefore, if the license manufacturer enters into an agreement with a contract manufacturing facility, the license manufacturer must ensure that the facility complies with the applicable standards. An agreement between a license manufacturer and a contract manufacturing facility normally includes procedures to regularly assess the contract manufacturing facility's compliance. These procedures may include, but are not limited to, review of records and manufacturing deviations and defects, and periodic audits.

For shared manufacturing arrangements, each manufacturer must submit a separate biologics license application describing the manufacturing facilities and operations applicable to the preparation of that manufacturer's biological substance or product (§ 601.2(a)). In the guidance, we state that we expect the manufacturer that prepares (or is responsible for the preparation of) the product in final form for commercial distribution to assume primary responsibility for providing data demonstrating the safety, purity, and potency of the final product. We also state that we expect the licensed finished product manufacturer to be primarily responsible for any postapproval obligations, such as postmarketing clinical trials, additional product stability studies, complaint handling, recalls, postmarket reporting of the dissemination of advertising and promotional labeling materials as required under § 601.12(f)(4) and adverse experience reporting. We recommend that the final product manufacturer establish a procedure with the other participating manufacturer(s) to obtain information in these areas.

Description of Respondents: The recordkeeping and reporting recommendations described in this document affect the participating licensed manufacturer(s), final product manufacturer(s), and contract manufacturer(s) associated with cooperative manufacturing arrangements.

Burden Estimate: We believe that the information collection provisions in the guidance do not create a new burden for respondents. We believe the reporting and recordkeeping provisions are part of usual and customary business practices. Licensed manufacturers would have contractual agreements with participating licensed manufacturers, final product manufacturers, and contract manufacturers, as applicable for the type of cooperative manufacturing arrangement, to address all these information collection provisions.

The guidance also refers to previously approved collections of information found in FDA regulations at parts 201, 207, 211, 600, 601, 606, 607, 610, 660, 801, 803, 807, 809, and 820 (21 CFR parts 201, 207, 211, 600, 601, 606, 607, 610, 660, 801, 803, 807, 809, and 820). The collections of information in §§ 606.121, 606.122, and 610.40 have been approved under OMB control number 0910–0116; § 610.2 has been approved under OMB control number 0910–0206; §§ 600.12(e) and 600.80 have been approved under OMB control number 0910–0308; §§ 601.2(a), 601.12, 610.60 through 610.65, 610.67, 660.2(c), 660.28(a) and (b), 660.35(a), (c) through (g), (i) through (m), 660.45, and 660.55(a) and (b) have been approved under OMB control number 0910–0338; §§ 803.20, 803.50, and 803.53 have been approved under OMB control number 0910–0437; and §§ 600.14 and 606.171 have been approved under OMB control number 0910–0458. The current good manufacturing practice regulations for finished pharmaceuticals (part 211) have been approved under OMB control number 0910–0139; §§ 820.181 and 820.184 have been approved under OMB control number 0910–0073; the establishment registration regulations (parts 207, 607, and 807) have been approved under OMB control numbers 0910–0045, 0910–0052, and 0910–0625; and the labeling regulations (parts 201, 801, and 809) have been approved under OMB control numbers 0910–0537, 0910–0572, and 0910–0485.

In the **Federal Register** of July 7, 2014 (79 FR 38318), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received no comments.

Dated: December 11, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29611 Filed 12–17–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1953]

Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the