only safe color additives will be used in foods, drugs, cosmetics, and medical devices sold in the United States. The required information is unique to the batch of color additive that is the subject of a request for certification. The manufacturer's batch number is used for temporarily identifying a batch of color additive until FDA issues a certification lot number and for identifying a certified batch during inspections. The manufacturer's batch number also aids in tracing the disposal of a certified batch or a batch that has been denied certification for noncompliance with the color additive regulations. The manufacturer's batch weight is used for assessing the certification fee. The batch weight also is used to account for the disposal of a batch of certified or certification-denied color additive. The batch weight can be used in a recall to determine whether all unused color additive in the batch has been recalled. The manufacturer's name and address and the name and address of the person requesting certification are used to contact the person responsible should a question arise concerning compliance with the color additive regulations. Information on storage conditions pending certification is used to evaluate whether a batch of certified color additive is inadvertently or intentionally altered in a manner that would make the sample submitted for certification analysis unrepresentative of the batch. We check storage information during inspections. Information on intended uses for a batch of color additive is used to assure that a batch of certified color additive will be used in accordance with the requirements of its listing regulation. The statement of the fee on a certification request is used for accounting purposes so that a person requesting certification can be notified promptly of any discrepancies.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
80.21; Request for Certification	35	199	6,965	0.17	1,184
80.22; Sample to accompany request	35	199	6,965	0.05	348
Total				0.22	1,532

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

TABLE 2—ESTIMATED RECORDKEEPING BURDEN [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
80.39; Record of Distribution	35	199	6,965	0.25	1,741

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

We base our estimate on our review of the certification requests received over the past 3 fiscal years (FY). The annual burden estimate for this information collection is 3,273 hours. The estimated reporting burden for this information collection is 1,532 hours and the estimated recordkeeping burden for this information collection is 1,741 hours. From FY 2011 to FY 2013, we processed an average of 6,954 responses (requests for certification of batches of color additives) per year. There were 35 different respondents, corresponding to an average of approximately 199 responses from each respondent per year. Using information from industry personnel, we estimate that an average of 0.22 hour per response is required for reporting (preparing certification requests and accompanying samples) and an average of 0.25 hour per response is required for recordkeeping.

Our Web-based Color Certification information system allows submitters to request color certification online, follow their submissions through the process, and obtain information on account status. The system sends back the certification results electronically, allowing submitters to sell their certified color before receiving hard-copy certificates. Any delays in the system result only from shipment of color additive samples to FDA's Office of Cosmetics and Colors for analysis.

Dated: January 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02513 Filed 2–5–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0085]

Draft 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 or the Agency) is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act.'' The draft guidance announced in this notice sets forth FDA's interpretation of the Food and Drug Administration Safety and Innovation Act (FDASIA), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to require that certain submissions under the FD&C Act and the Public Health Service Act be submitted in electronic format specified by FDA, beginning no earlier than 24 months after publication of a final version of the draft guidance. This guidance describes how FDA interprets and plans to implement the electronic submission requirements.

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 May 7, 2014.

ADDRESSES: Submit written requests for single copies of the documents to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the documents.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1160, Silver Spring, MD 20993, *ronald.fitzmartin@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act.'' FDASIA (Pub. L. 112–144), signed by the President on July 9, 2012, amended the FD&C Act to add section 745A entitled ''Electronic Format for Submissions.'' Drug and biologic submissions are addressed in section 745A(a).

Section 745A(a)(1) of the FD&C Act describes the general scope of section 745A(a) and provides that submissions under new drug applications (NDAs), abbreviated new drug applications (ANDAs), biological license applications (BLAs), and investigational new drug applications (INDs) must be in electronic format specified in FDA guidance. Section 745A(a)(2) states that the guidance issued by FDA may provide a timetable for future standards and criteria for waivers and exemptions. Section 745A(a)(3) provides that submissions under section 561 are exempt from the requirements of section 745A(a).

This guidance describes the scope of section 745A(a), the waivers of and exemptions from the electronic submission requirements, and the process and timetable that FDA will use to implement the electronic submission requirements. As described in the guidance, FDA will develop individual guidances to specify the electronic formats for certain submissions under section 745A(a). Under section 745A(a)(1) of the FD&C Act, electronic submissions can be required no earlier than 24 months after a final guidance is issued. Therefore, no earlier than 24 months after issuance of the final version of an individual guidance specifying the format for certain submissions under section 745A(a), the Agency will begin requiring that the submissions under NDAs, ANDAs, BLAs, or INDs be submitted in the specified electronic format.

The required format(s) for specific submissions and corresponding timetable(s) for implementation will be specified in individual guidances. Once an individual guidance is finalized and the timetable for implementation described in that guidance has passed, the guidance is considered to have binding effect and the electronic format(s) specified in that guidance must be used for submissions under certain NDAs, ANDAs, BLAs, or INDs.

In section 745A(a) of the FD&C Act, Congress granted explicit statutory authorization to FDA to specify in guidance the format for the electronic submissions required under this section. Accordingly, to the extent that this draft guidance provides such requirements under section 745A(a) of the FD&C Act, indicated by the use of the words ''must'' or ''required'', this document 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). FDA guidances ordinarily contain standard language explaining that guidances should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. FDA is not including this standard language in this guidance because this draft guidance contains binding provisions. The draft guidance, when finalized, will represent the Agency's current thinking on providing regulatory submissions in electronic format, as required under section 745A(a) of the FD&C Act.

II. Paperwork Reduction Act of 1995

This draft guidance contains no collection of information. As discussed in the draft guidance, FDA intends to develop individual draft guidances to specify the electronic formats for certain submissions under section 745A(a). We will discuss any information collection subject to clearance by OMB under the Paperwork Reduction Act in each **Federal Register** notice announcing the availability of the individual draft guidances that specify the required electronic formats.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments 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 *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatory Information/Guidances/default.htm*, or *http://www.regulations.gov.*

Dated: January 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0097]

Revised Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Standardized Study Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled ''Providing