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

availability of a guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act.'' The 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, beginning no earlier than 24 months after issuance of a final version of a guidance document specifying the format for such electronic submissions. This guidance describes how FDA interprets and plans to implement the electronic submission requirements and finalizes the draft guidance that was issued on February 6, 2014.

DATES: Submit either electronic or written comments on Agency guidances at any time.

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, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 71, Rm. 3128, 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 documents.

Submit electronic comments on the 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. 1192, Silver Spring, MD 20993–0002, *ronald.fitzmartin@fda.hhs.gov;* or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act.'' Section 1136 of 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'' (21 U.S.C. 379k–1). Drug and biological product submissions are addressed in section 745A(a) of the FD&C Act.

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), biologics license applications (BLAs), and investigational new drug applications (INDs) must be in electronic format specified in FDA guidance. Section 745A(a)(2) of the FD&C Act states that the guidance issued by FDA may provide a timetable for future standards and criteria for waivers and exemptions. Section 745A(a)(3) of the FD&C Act provides that the electronic submission requirements in section 745A(a) do not apply to submissions under section 561 of the FD&C Act (21 U.S.C.360bbb).

This guidance describes FDA's interpretation of the scope of section 745A(a) of the FD&C Act. It announces that certain INDs will be exempted from the electronic submission requirements. Finally, it describes 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 types of 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 FDA issues a final guidance. Therefore, no earlier than 24 months after issuance of the final version of an individual guidance specifying the format for certain types of submissions under section 745A(a) of the FD&C Act, the Agency will begin requiring that the submissions under NDAs, ANDAs, certain BLAs, and certain INDs be submitted in the specified electronic format for the types of submissions described in that guidance.

Individual guidances will be developed to specify the electronic formats, subject matter, and scope of applicability for certain submissions under section 745A(a) of the FD&C Act. Once an individual guidance is finalized and the timetable for implementation described in that guidance has passed, the guidance will have binding effect and the electronic format(s) specified in that guidance must be used for submissions to NDAs, ANDAs, certain BLAs, and certain INDs.

In the **Federal Register** of February 6, 2014 (79 FR 7200), FDA announced a draft version of this guidance entitled ''Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act.'' The comment period on the draft guidance ended on May 6, 2014. We reviewed all comments received on the draft guidance and revised several sections of the guidance. The updates include:

Section III.A and III.B: Clarified that the scope of the requirement under section 754A(a) does not extend to certain INDs and certain BLAs. Also clarified that certain INDs are exempted from the electronic submission requirements under section 745A(a)(2). Specifically, we clarified that INDs and BLAs for devices that are regulated by CBER as biological products under Section 351 of the Public Health Service (PHS) Act are instead subject to the requirements under Section 745A(b), and that, issued in section 745A(a)(2), INDs that are noncommercial are exempt from the requirements under section 745A(a). We provided examples in this regard.

Section III.D: Clarified that the individual guidances under 745A(a) will specify electronic formats, subject matter, and scope of applicability, as well as the timetable for implementation.

Section III.F: Clarified the timetable under which revisions or updates to electronic submission standards will take effect.

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 guidance contains binding provisions. In section 745A(a) of the FD&C Act, Congress granted explicit authorization to FDA to specify in guidance the format for the electronic submissions required under that section. Accordingly, this guidance explains such requirements under section 745A(a) of the FD&C Act, indicated by the use of the words must or required, and therefore 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

This guidance contains no collection of information. As discussed in the guidance, FDA intends to develop individual guidances to specify the electronic formats for certain submissions under section 745A(a) of the FD&C Act. 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 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/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. 2014–29609 Filed 12–17–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Complementary and Alternative Medicine.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Complementary and Alternative Medicine

Date: February 6, 2015.

Closed: 8:30 a.m. to 9:45 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Open: 10:00 a.m. to 4:00 p.m.

Agenda: Report from the Institute Director and other staff.

Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Martin H. Goldrosen, Ph.D., Director, Division of Extramural Activities, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Blvd., Ste. 401, Bethesda, MD 20892–5475, (301) 594–2014, *goldrosm@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *nccam.nih.gov/about/naccam/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: December 12, 2014.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–29571 Filed 12–17–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD); Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Child Health and Human Development Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. A portion of this meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review and discussion of grant applications. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below in advance of the meeting.

Name of Committee: National Advisory Child Health and Human Development Council.

Date: January 22, 2015.

Open: January 22, 2015, 8:00 a.m. to 12:10 p.m.

Agenda: Report of the Director, NICHD; Report of the Acting Director, Division of Extramural Research, NICHD; Discussion of the Outstanding Investigator Award (R35); and New Business of the Council.

Closed: January 22, 2015, 1:15 p.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Center Drive, C-Wing, Conference Room 6, Bethesda, MD 20892.

Contact Person: Caroline Signore, MD., Mp.H., Acting Director, Division of Extramural Research, *Eunice Kenney Shriver* National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 4A05, MSC 7510, Bethesda, MD 20892, (301) 496–5577.

Any interested person may file written comments with the committee by forwarding the statement to the contact person listed on this notice. The statement should include the name, address, telephone number, and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance