17, 2013 (Docket No. FDA–2013–P–0886), under 21 CFR 10.30, requesting that the Agency determine whether JADELLE (levonorgestrel) implant, 75 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that JADELLE (levonorgestrel) implant, 75 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that JADELLE (levonorgestrel) implant, 75 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of JADELLE (levonorgestrel) implant, 75 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list JADELLE (levonorgestrel) implant, 75 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to JADELLE (levonorgestrel) implant, 75 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–20634 Filed 8–28–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–S–0009]

Draft Guidance for Industry: Electronic Submission of Lot Distribution Reports; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Electronic Submission of Lot Distribution Reports'' dated August 2014. The draft guidance document provides information and recommendations pertaining to the electronic submission of lot distribution reports for applicants with approved biologics license applications (BLAs). FDA recently published in the **Federal Register** a final rule requiring that, among other things, lot distribution reports be submitted to FDA in an electronic format that the Agency can process, review, and archive. The draft guidance, when finalized, is intended to help licensed manufacturers of products distributed under approved BLAs (henceforth referred to as applicants) comply with the final rule.

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 November 28, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to 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 or 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. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800 or CDER at 301–796–3400. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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: Lori J. Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911 or Jared Lantzy, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1116, Silver Spring, MD 20993–0002, email: *esub@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Electronic Submission of Lot Distribution Reports'' dated August 2014. The draft guidance provides information and recommendations pertaining to the electronic submission of lot distribution reports. The draft guidance provides information on how to electronically submit lot distribution reports for biological products under approved BLAs for which CBER or CDER has regulatory responsibility. When finalized, this guidance will not apply to any other biological product.

FDA recently published in the **Federal Register** of June 10, 2014 (79 FR 33072), a final rule requiring electronic submission of certain postmarketing submissions. Among other things, under this rule applicants are required to submit biological lot distribution reports to FDA in an electronic format that the Agency can process, review, and archive. The draft guidance, when finalized, is intended to help applicants subject to lot distribution reporting comply with the final rule. Along with other information, the draft guidance provides updated information about the following: (1) Structured Product Labeling standard and vocabulary for electronic submission of lot distribution reporting; (2) additional resources such as implementation guide, validation procedures; and links with further information; and (3) procedures for requesting temporary waivers from the electronic submission requirement.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. 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 600.81 and

600.90 have been approved under OMB control number 0910–0308.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. 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 draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov*.

Dated: August 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–20635 Filed 8–28–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Advisory Committee on Training in Primary Care Medicine and Dentistry; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD).

Dates and Times: September 15, 2014, 9:00 a.m.–2:00 p.m. (EST).

Place: Webinar and Conference Call Format.

Status: The meeting will be open to the public.

Purpose: The ACTPCMD provides advice and recommendations on a broad range of issues related to grant programs authorized by sections 222 and 749 of the Public Health Service Act, as amended by section 5103(d) and redesignated by section 5303 of the Patient Protection and Affordable Care Act of 2010.

Agenda: This webinar meeting will begin with opening remarks from Health Resources and Service Administration (HRSA) senior officials and include a final discussion and vote on the committee's 11th Report to Congress. Additional agenda items include: review of a letter of support for the Teaching Health Center Graduate Medical Education program, a brief program update by HRSA staff, and discussion on a topic for the committee's next report.

The agenda will be available 2 days prior to the meeting on the HRSA Web site (*http://www.hrsa.gov/advisorycommittees/bhpradvisory/actpcmd/index.html*). Agenda items are subject to change as priorities dictate.

Public Comment: An opportunity will be provided for public comment at the end of the meeting, or written comments to the members may be sent, not later than five days prior to the meeting date, to Shane Rogers at *srogers@hrsa.gov.* As this meeting will be conducted via webinar format, a Question and Answer Pod will also be available for public comment as well.

SUPPLEMENTARY INFORMATION: Information on accessing the webinar will be available via the following Web site not later than two days prior to the meeting date: *http://www.hrsa.gov/advisorycommittees/bhpradvisory/actpcmd/index.html.*

FOR FURTHER INFORMATION CONTACT: Mr. Shane Rogers, Designated Federal Official, ACTPCMD, Bureau of Health Workforce, Health Resources and Services Administration, Room 12C–06, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, call 301–443–5260, or email *srogers@hrsa.gov.*

Dated: August 22, 2014.

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2014–20599 Filed 8–28–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: Council on Graduate Medical Education (COGME).

Dates and Times: September 12, 2014, 9:00 a.m.–3:00 p.m. (EST).

Place: Webinar and Conference Call Format.

Status: The meeting will be open to the public.

Purpose: The COGME provides advice and recommendations to the Secretary of the Department of Health and Human Services and to Congress on a range of issues including the supply and distribution of physicians in the United States, current and future physician shortages or excesses, issues relating to foreign medical school graduates, the nature and financing of medical education training, and the development of performance measures and longitudinal evaluation of medical education programs.

Agenda: This webinar meeting will begin with opening remarks from Health Resources and Service Administration (HRSA) senior officials and include a vote on the Council's next Vice Chair. The meeting will also include discussion on the Council's 22nd Report to Congress as well as a brief update by the Designated Federal Official on the Council's current status.

The agenda will be available 2 days prior to the meeting on the HRSA Web site (*http://www.hrsa.gov/advisorycommittees/bhpradvisory/cogme/index.html*). Agenda items are subject to change as priorities dictate.

Public Comment: An opportunity will be provided for public comment at the end of the meeting, or written comments to the members may be sent, no later than 5 days prior to the meeting date, to Shane Rogers at *srogers@hrsa.gov.* As this meeting will be conducted via webinar format, a Question and Answer Pod will also be available for public comment as well.

SUPPLEMENTARY INFORMATION: Information on accessing the webinar will be available via the following Web site no later than 2 days prior to the meeting date: *http://www.hrsa.gov/advisorycommittees/bhpradvisory/cogme/index.html.*

FOR FURTHER INFORMATION CONTACT: Mr. Shane Rogers, Designated Federal Official, COGME, Bureau of Health Workforce, Health Resources and Services Administration, Room 12C–06, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, call 301–443–5260, or email *srogers@hrsa.gov.*