DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Ave
Building 51
Silver Spring, MD 20993

AUG 29 2014

Alan G. Minsk
Kelley C. Nduom
Arnall Golden Gregory LLP
171 17th Street, NW
Suite 2100
Atlanta, GA 30363

Re: Docket No. FDA-2013-P-0886

Dear Mr. Minsk and Ms. Nduom:

This letter responds to your citizen petition received on July 24, 2013, requesting that the Food and Drug Administration (FDA) determine that JADELLE (levonorgestrel) implant, 75 milligrams (mg) (new drug application 20-544), was voluntarily withdrawn from the market for reasons other than safety or effectiveness.

FDA has reviewed its records and determined that JADELLE (levonorgestrel) implant, 75 mg, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain JADELLE (levonorgestrel) implant, 75 mg, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-4455.

Sincerely,

Nisha P. Shah
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

It is ACF's policy to integrate both use of existing evidence and opportunities for further learning into all of our activities. Where an evidence base is lacking, we will build evidence through strong evaluations. Where evidence exists, we will use it. Discretionary funding opportunity announcements will require that successful applicants cooperate with any Federal evaluations if selected to participate. As legally allowed, programs with waiver authorities should require rigorous evaluations as a condition of waivers. As appropriate, ACF will encourage, incentivize, or require grantees to use existing evidence of effective strategies in designing or selecting service approaches. The emphasis on evidence is meant to support, not inhibit, innovation, improvement, and learning.

Transparency: ACF will make information about planned and ongoing evaluations easily accessible, typically through posting on the web information about the contractor or grantee conducting the work and descriptions of the evaluation questions, methods to be used, and expected timeline for reporting results. ACF will present information about study designs, implementation, and findings at professional conferences.

Study plans will be published in advance. ACF will release evaluation results regardless of the findings. Evaluation reports will describe the methods used, including strengths and weaknesses, and discuss the generalizability of the findings. Evaluation reports will present comprehensive results, including favorable, unfavorable, and null findings. ACF will release evaluation results timely—usually within 2 months of a report's completion.

ACF will archive evaluation data for secondary use by interested researchers, typically through building requirements into contracts to prepare data sets for secondary use.

Independence: Independence and objectivity are core principles of evaluation.[1] Agency and program leadership, program staff, service providers, and others should participate actively in setting evaluation priorities, identifying evaluation questions, and assessing the implications of findings. However, it is important to insulate evaluation functions from undue influence and from both the appearance and the reality of bias. To promote objectivity, ACF protects independence in the design, conduct, and analysis of evaluations. To this end:

- ACF will conduct evaluations through the competitive award of grants and contracts to external experts who are free from conflicts of interest.
- The director of OPRE reports directly to the Assistant Secretary for Children and Families; has authority to approve the design of evaluation projects and analysis plans; and has authority to approve, release, and disseminate evaluation reports.

Ethics: ACF-sponsored evaluations will be conducted in an ethical manner and safeguard the dignity, rights, safety, and privacy of participants. ACF-sponsored evaluations will comply with both the spirit and the letter of relevant requirements such as regulations governing research involving human subjects.

Mark H. Greenberg,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2014–20616 Filed 8–28–14; 8:45 am]

BILLING CODE 4184–79–P

[1] American Evaluation Association, "An Evaluation Roadmap for a More Effective Government", November 2013, *http://www.eval.org/d/do/472*, accessed 16 December 2013, and Government Accountability Office, "Employment and Training Administration: Increased Authority and Accountability Could Improve Research Program", GAO–10- 243, January 2010, *http://www.gao.gov/products/GAO-10-243*, accessed 18 June 2012.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–0886]

Determination That JADELLE (Levonorgestrel) Implant, 75 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) has determined that JADELLE (levonorgestrel) implant, 75 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for JADELLE (levonorgestrel) implant, 75 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nisha Shah, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993–0002, 301–796–4455.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

JADELLE (levonorgestrel) implant, 75 mg, is the subject of NDA 20–544, held by Population Council, and initially approved on November 1, 1996. JADELLE (levonorgestrel) implants, 75 mg, are indicated for the prevention of pregnancy and are a long-term (up to 5 years) reversible method of contraception.

Population Council has never marketed JADELLE (levonorgestrel) implant, 75 mg. Therefore, as in previous instances (see e.g., 72 FR 9763, 61 FR 25497), the Agency has determined, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Arnall Golden Gregory, LLP submitted a citizen petition dated July

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