and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective: June 23, 2004. FDA has verified the Arena Pharmaceuticals, Inc. claim that June 23, 2004, is the date the investigational new drug application became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 22, 2009. The applicant claims December 18, 2009, as the date the NDA for BELVIQ was initially submitted. However, FDA records indicate that NDA 22–529 was submitted on December 22, 2009.

3. *The date the application was approved:* June 27, 2012. FDA has verified the applicant's claim that NDA 22–529 was approved on June 27, 2012. FDA has verified the applicant's claim that NDA 22–529 was approved on June 27, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,174 days; 1,051 days; or 352 days of patent term extension, respectively.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: September 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22937 Filed 9–22–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0881]

Self-Identification of Generic Drug Facilities, Sites, and Organizations; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Self-Identification of Generic Drug Facilities, Sites, and Organizations.'' On July 9, 2012, the Generic Drug User Fee Amendments of 2012 (GDUFA) was signed into law by the President. GDUFA, designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry, requires that generic drug facilities, sites, and organizations around the world provide identification information annually to FDA. This guidance is intended to assist industry to meet the self-identification requirement. It explains who is required to self-identify, what information must be requested, how the information should be submitted to FDA, and what the penalty is for failure to self-identify.

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

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2012–D–0881 for ''Self-Identification of Generic Drug Facilities, Sites, and Organizations.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/*

regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Andrew LeBoeuf, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–0503.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Self-Identification of Generic Drug Facilities, Sites, and Organizations.'' The guidance announced in this notice finalizes the draft guidance of the same name announced in the **Federal Register** of August 27, 2012 (77 FR 51811). Compared to the draft guidance, the final guidance clarifies various matters, including that the self-identification requirements have been implemented, and simplifies the instructions for electronic submission of self-identification information. FDA received one comment on the draft guidance, which was considered as the guidance was finalized.

On July 9, 2012, GDUFA (Pub. L. 112–144, Title III) was signed into law by the President. GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. GDUFA enables FDA to assess user fees to support critical and measurable enhancements to FDA's generic drugs program. GDUFA will also significantly improve global supply chain transparency by requiring owners of facilities producing generic drug products, active pharmaceutical ingredients (API), and certain other sites and organizations that support the manufacture or approval of these products to electronically self-identify with FDA and update that information annually.

Self-identification is required for two purposes. First, it is necessary to determine the universe of facilities required to pay user fees. Second, self-identification is a central component of an effort to promote global supply chain transparency. The information provided through self-identification enables quick, accurate, and reliable surveillance of generic drugs and facilitates inspections and compliance.

Most facilities that self-identify are required to pay an annual facility user fee. These include facilities manufacturing, or intending to manufacture, API of human generic drugs and/or finished dosage form (FDF) human generic drugs. Other facilities, sites, and organizations must self-identify, but are not required to pay the annual facility user fee. These include facilities that solely manufacture positron emission tomography drugs, or sites and organizations that only perform testing, repackaging, or relabeling operations. Please note that while re-packagers are not required to pay user fees, packagers are, in most cases, FDF manufacturers and subject to facility fees.

A separate system for the electronic self-identification of generic industry facilities, sites, and organizations was established for GDUFA. Entities required to register and list (under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) or section 351 of the Public Health Service Act (42 U.S.C. 262)), and those required to self-identify under GDUFA, submit information separately to the respective systems. Each system populates its own database to meet unique requirements and deadlines. The new GDUFA system uses the same platform and technical standards already familiar to manufacturers required to register and list.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Self-Identification of Generic Drug Facilities, Sites, and Organizations.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: September 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22944 Filed 9–22–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Tribal Consultation and Urban Confer Sessions on the State of the Great Plains Area Indian Health Service; Extension of Comment Period

AGENCY: Indian Health Service, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: This document extends the comment period in the Notice of Tribal Consultation and Urban Confer Sessions on the State of the Great Plains Area Indian Health Service announcement that was published in the **Federal Register** on June 3, 2016.

DATES: The comment period has been extended to November 30, 2016.

FOR FURTHER INFORMATION CONTACT: Roselyn Tso, Acting Director, Office of Direct Service and Contracting Tribes, Indian Health Service, 5600 Fishers Lane, Mail Stop 08E17, Rockville, MD 20857, telephone (301) 443–1104. (This is not a toll-free number.)

Dated: September 16, 2016.

Mary Smith,

Principal Deputy Director, Indian Health Service.

[FR Doc. 2016–22922 Filed 9–22–16; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following 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,