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 The guidance announced in this notice finalizes the draft guidance of the same name announced in the **Federal Register** of August 27, 2012 (77 FR 51811). Compared to the draft guidance, the final guidance clarifies various matters, including that the self-identification requirements have been implemented, and simplifies the instructions for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 FDA received one comment on the draft guidance, which was considered as the guidance was finalized.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]

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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,