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Submit written requests for single copies of the revised draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ebla Ali Ibrahim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6308, Silver Spring, MD 20993, 301–796–0281; or Stephen Ripley, 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 Peter Hudson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G434 (HFZ–410), Silver Spring, MD, 20993–0002, 301–796–6440.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Assay Development and Validation for Immunogenicity Testing of Therapeutic Protein Products.'' Patient immune responses to therapeutic protein products have the potential to affect product safety and efficacy. The clinical effects of patient immune responses are highly variable, ranging from no effect at all to extreme harmful effects to patient health. Detection and analysis of ADA formation is a helpful tool in understanding potential patient immune responses. Information on immune responses observed during clinical trials, particularly the incidence of ADA induction and the implications of ADA responses for drug safety and efficacy, is crucial for any therapeutic product development program. Accordingly, such information, if applicable, should be included in the prescribing information as a subsection of the ADVERSE REACTIONS section entitled ''Immunogenicity.''

In general, assays for detection of ADA facilitate understanding of the immunogenicity, safety, and efficacy of therapeutic protein products. However, the detection of ADA is dependent on key operating parameters of the assays (*e.g.,* sensitivity, specificity), which vary between assays. Therefore, the development of valid, sensitive, specific, and selective assays to measure ADA responses is a key aspect of therapeutic protein product development.

This guidance revises the draft guidance for industry entitled ''Assay Development for Immunogenicity Testing of Therapeutic Proteins'' issued in December 2009. The information in the draft guidance has been reorganized for clarity, and the revised draft guidance includes new information on titering and confirmatory assays.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on assay development and validation for immunogenicity testing of therapeutic protein products. 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. Paperwork Reduction Act of 1995

This revised draft guidance refers to previously approved collections of information that 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 part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control numbers 0910–0001 and 0910–0230; the collections of information in 21 CFR part 58 have been approved under OMB control number 0910–0119; and the collections of information in 21 CFR part 601 have been approved under OMB control numbers 0910–0338 and 0910–0719.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm,* or *http://www.regulations.gov*.

Dated: April 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09449 Filed 4–22–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–P–3299]

Determination That THALITONE (Chlorthalidone USP) Tablets, 15 Milligrams, Were 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 Agency) has determined that THALITONE (chlorthalidone USP) tablets, 15 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for

chlorthalidone USP tablets, 15 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Christopher Koepke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6214, Silver Spring, MD 20993–0002, 240–402–3543.

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 (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.

THALITONE (chlorthalidone USP) tablets, 15 mg, are the subject of NDA 19–574, held by Citron Pharma LLC, and initially approved on December 20, 1988. THALITONE is indicated for the management of hypertension either alone or in combination with other antihypertensive drugs. Chlorthalidone is indicated as an adjunctive therapy in edema associated with congestive heart failure, hepatic cirrhosis, and corticosteroid and estrogen therapy. Chlorthalidone has also been found useful in edema due to various forms of renal dysfunction such as nephrotic syndrome, acute glomerulonephritis, and chronic renal failure.

THALITONE (chlorthalidone USP) tablets, 15 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Clinipace Worldwide submitted a citizen petition dated September 9, 2015 (Docket No. FDA–2015–P–3299), under 21 CFR 10.30, requesting that the Agency determine whether THALITONE (chlorthalidone USP) tablets, 15 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information, FDA has determined under § 314.161 that THALITONE (chlorthalidone USP) tablets, 15 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that THALITONE (chlorthalidone USP) tablets, 15 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of THALITONE (chlorthalidone USP) tablets, 15 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 THALITONE (chlorthalidone USP) tablets, 15 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 THALITONE (chlorthalidone USP) tablets, 15 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: April 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09450 Filed 4–22–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60-Day Information Collection: Indian Self-Determination and Education Assistance Act Contracts

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments. Request for extension of approval.

SUMMARY: In compliance the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to comment on the information collection titled, ''Indian Self-Determination and Education Assistance Act Contracts,'' Office of Management and Budget (OMB) Control Number 0917–0037. IHS is requesting OMB to approve an extension for this collection, which expires on July 31, 2016.

DATES: C*omment Due Date:* June 24, 2016. Your comments regarding this information collection are best assured of having full effect if received within 60 days of the date of this publication.

ADDRESSES: Send your written comments, requests for more information on the collection, or requests to obtain a copy of the data collection instrument and instructions to Mr. Chris Buchanan by one of the following methods:

- *Mail:* Mr. Chris Buchanan, Director, IHS Office of Direct Services and Contracting Tribes (ODSCT), Indian Health Service, 5600 Fishers Lane, Mail Stop O8E17C, Rockville, MD 20857.
- *Phone:* 301–443–1104.
- *Email: Chris.Buchanan@ihs.gov*.
- *Fax:* 301–480–3192.

SUPPLEMENTARY INFORMATION: This previously approved information collection project was last published in the **Federal Register** (78 FR 32405), as a joint submission with the Bureau of Indian Affairs (BIA), under OMB Control Number 1076–0136, on May 30, 2013 and allowed 30 days for public comment. No public comment was received in response to the notice. On July 31, 2013, the IHS obtained its own OMB Control Number, 0917–0037, for this information collection and is now publishing a separate notice from the BIA in the **Federal Register**. The purpose of this notice is to allow 60 days for public comment. A copy of the supporting statement is available at *www.regulations.gov* (see Docket ID IHS–2016–0003).