the ALJ should not have allowed the objectors to litigate the issue. However, because Lannett may be entitled to the issuance of a rule authorizing the importation, I conclude that it is appropriate to issue a declaratory order on the issue of whether Lannett has established its entitlement to be registered. *See* 5 U.S.C. § 554(e) (''The agency, with like effect as in the case of other orders, and in its sound discretion, may issue a declaratory order to terminate a controversy or remove uncertainty.'').

Pursuant to section 303(a) of the CSA, ''[t]he Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with the United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.'' 21 U.S.C. § 823(a). ''In determining the public interest,'' section 303(a) directs the Attorney General to consider the following factors:

(1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substances in schedule I or II compounded there from into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with public health and safety.

Id. It is well settled that the Agency need not make findings as to all of the factors and that it may give each factor the weight it deems appropriate in determining the public interest. *See Novelty, Inc.,* v. *DEA,* 571 F.3d 1176, 1181 (D.C. Cir. 2009).

While there is insufficient evidence to make findings with respect to factors two, three, and six, the record establishes that Lannett has experience in the manufacture and development of pharmaceutical products and that it maintains effective controls against diversion (factor five). The record also establishes that Lannett has not been convicted of an offense related to the manufacture or distribution of controlled substances (factor four). Both of these findings support the conclusion that granting Lannett's application for a registration would be consistent with the public interest.

The ALJ found that Lannett had not shown that competition among domestic manufactures of dronabinol is inadequate and that the current manufacturers were incapable of producing an adequate and uninterrupted supply of this substance (factor one). Relying on *Lyle E. Craker,* 74 FR 2101 (2009), the ALJ thus concluded this factor ''weighs strongly against a finding that Lannett's registration would be in the public interest,'' and concluded that the record does not support granting its application.

I conclude, however, that *Craker* does not require that Lannett's application be denied. As the D.C. Circuit has held, ''section 823(a)'s enumerated factors represent components of the public interest rather than independent requirements for registration and thus, the [Agency] may find a registration consistent with the public interest even if one (or possibly more) of the public interest factors is not satisfied.'' *Penick,* 491 F.3d at 490. As *Penick* recognized, the principal purpose of factor one is to provide the Agency with authority ''to maintain control over diversion 'by limiting the [number of firms engaged in the] importation and bulk manufacture' of controlled substances.'' *Id.* at 491.

Craker involved an application to manufacture a schedule I controlled substance on a continuing basis. By contrast, the activity for which Lannett seeks an importer's registration (to perform stability and bioequivalency testing) does not involve an activity of a continuing nature, but rather, three separate acts (at most) of importation. As such, granting its application does not raise the same concerns with respect to the Agency's ability to maintain effective controls against diversion.

Accordingly, I conclude that factor one does not preclude the issuance of an import registration to Lannett, subject to the condition that its authority to import dronabinol as a schedule I drug be limited to the quantity which is necessary to support an ANDA.[30] I therefore conclude that upon providing adequate justification for the quantity of the importation, Lannett's registration would be consistent with the public interest.[31] 21 U.S.C. § 823(a).

Order

Lannett is hereby directed to file with this Office its testing protocol and an itemization setting forth the various quantities it needs to import for bioequivalency and stability studies, as well as reserves. If FDA requires that it import the entire batch that will be used for bioequivalency and stability testing and will not permit it to select its test samples from the production batch and import only those quantities, Lannett should provide evidence supporting this. Finally, if Lannett intends to pursue importation of the additional batches, it must provide additional justification for doing so. Lannett must serve a copy of all filings on the objectors. Lannett's submission shall be due no later than 90 days from date of the issuance of this Order; Lannett shall timely inform this Office of any delays in obtaining a response from FDA.[32] It is further ordered that Lannett's application for a registration to import dronabinol be held in abeyance.

Dated: November 15, 2012

Michele M. Leonhart

Administrator

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BILLING CODE 4410–09–P

[30] DEA has long held that it has authority to impose conditions on a registration. *See Alfred Khalily,* 64 FR 31289 (1999); *Gordon M. Acker, D.M.D.,* 53 FR 50309 (1988).

[31] Nor does the record establish any reason why granting Lannett's application would be inconsistent with the United States' obligations under international treaties and the Single Convention. *See Penick Corp.,* 491 F.3d at 492–93.

[32] The Objectors shall have thirty days from the date of receipt of Lannett's filing to submit a response.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

169th Meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans; Notice of Meeting

Pursuant to the authority contained in Section 512 of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1142, the 169th open meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans (also known as the ERISA Advisory Council) will be held on November 4–5, 2013.

The meeting will take place in C5521 Room 4, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210 on November 4, from 1 p.m. to approximately 5:00 p.m. On November 5, the meeting will start at 8:30 a.m. and conclude at approximately 4:00 p.m., with a break for lunch. The morning session on November 5 will be in C5521 Room 1. The afternoon session on November 5 will take place in Room S–2508 at the same address. The purpose of the open meeting on November 4 and the morning of November 5 is for the Advisory Council members to finalize the recommendations they will present to the Secretary. At the November 5 afternoon session, the Council members will receive an update from the Assistant Secretary of Labor for the Employee Benefits Security Administration (EBSA) and present their recommendations.

The Council recommendations will be on the following issues: (1) Successful Retirement Plan Communications for Various Population Segments, (2) Locating Missing and Lost Participants, and (3) Private Sector Pension De-risking and Participant Protections. Descriptions of these topics are available on the Advisory Council page of the EBSA Web site at *http://www.dol.gov/ebsa/aboutebsa/erisa_advisory_council.html.*

Organizations or members of the public wishing to submit a written statement may do so by submitting 30 copies on or before October 28, 2013 to Larry Good, Executive Secretary, ERISA Advisory Council, U.S. Department of Labor, Suite N–5623, 200 Constitution Avenue NW., Washington, DC 20210. Statements also may be submitted as email attachments in text or pdf format transmitted to *good.larry@dol.gov*. It is requested that statements not be included in the body of an email. Statements deemed relevant by the Advisory Council and received on or before October 28 will be included in the record of the meeting and made available in the EBSA Public Disclosure Room. Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed.

Individuals or representatives of organizations wishing to address the Advisory Council should forward their requests to the Executive Secretary or telephone (202) 693–8668. Oral presentations will be limited to ten minutes, time permitting, but an extended statement may be submitted for the record. Individuals with disabilities who need special accommodations should contact the Executive Secretary by October 28, 2013 at the address indicated.

Signed at Washington, DC, this 17th day of October, 2013.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration.

[FR Doc. 2013–24626 Filed 10–21–13; 8:45 am]

BILLING CODE 4510–29–P

OFFICE OF MANAGEMENT AND BUDGET

Calendar Year 2013 Cost of Outpatient Medical, Dental, and Cosmetic Surgery Services Furnished by Department of Defense Medical Treatment Facilities; Certain Rates Regarding Recovery From Tortiously Liable Third Persons

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Notice.

SUMMARY: By virtue of the authority vested in the President by section 2(a) of Public Law 87–603 (76 Stat. 593; 42 U.S.C. 2652), and delegated to the Director of the Office of Management and Budget (OMB) by the President through Executive Order No. 11541 of July 1, 1970, the rates referenced below are hereby established. These rates are for use in connection with the recovery from tortiously liable third persons for the cost of outpatient medical, dental and cosmetic surgery services furnished by military treatment facilities through the Department of Defense (DoD). The rates were established in accordance with the requirements of OMB Circular A–25, requiring reimbursement of the full cost of all services provided. *The CY13 Outpatient Medical, Dental, and Cosmetic Surgery rates* referenced are effective upon publication of this notice in the **Federal Register** and will remain in effect until further notice. Previously published inpatient rates remain in effect until further notice. Pharmacy rates are updated periodically. A full disclosure of the rates is posted at the DoD's Uniform Business Office Web site: *http://www.tricare.mil/ocfo/mcfs/ubo/mhs_rates.cfm.*

Sylvia M. Burwell,

Director.

[FR Doc. 2013–24330 Filed 10–21–13; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

[Docket No. 50–391; NRC–2008–0369]

Tennessee Valley Authority; Watts Bar Nuclear Plant, Unit 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Environmental assessment and finding of no significant impact; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering extending the latest construction completion date specified in Construction Permit No. CPPR–92 issued to Tennessee Valley Authority (permittee, TVA) for the Watts Bar Nuclear Plant (WBN), Unit 2.

ADDRESSES: Please refer to Docket ID NRC–2008–0369 when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this action by the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0369. Address questions about NRC dockets to Carol Gallagher; telephone: 301–287–3422; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search*.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced. The request to extend the construction permit expiration date, dated May 17, 2012, is available electronically in ADAMS under Accession No. ML12143A346.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is considering extending the latest construction completion date specified in Construction Permit No. CPPR–92 issued to Tennessee Valley Authority (permittee, TVA) for the Watts Bar Nuclear Plant (WBN), Unit 2. The facility is located at the permittee's site on the west branch of the Tennessee River approximately 50 miles northeast of Chattanooga, Tennessee. Therefore, as required by section 51.21 of Title 10 of the *Code of Federal Regulations* (10 CFR), the NRC performed an environmental assessment. Based on the results of the environmental assessment that follows, the NRC has determined not to prepare an environmental impact statement for the action of extending the completion date of the construction permit, and is issuing a finding of no significant impact.

II. Environmental Assessment

Identification of the Proposed Action

The proposed action would extend the latest construction completion date of Construction Permit No. CPPR–92 from March 31, 2013, to September 30, 2016. TVA submitted the construction permit request by letter dated May 17, 2012 (ADAMS Accession No. ML12143A346). TVA submitted the request to extend the construction permit at least 30 days before the expiration of the existing permit, therefore, in accordance with 10 CFR 2.109(a), the existing construction permit will remain in effect until the NRC staff has completed the review of the request.