

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
810.14	2	1	2	16	32
810.15(a) through (d)	2	1	2	16	32
810.15(e)	10	1	10	1	10
810.16	2	12	24	40	960
810.17	2	1	2	8	16
Total					1,082

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

The following burden estimates are based on FDA's experience with voluntary recalls under 21 CFR part 7. FDA expects no more than two mandatory recalls per year, as most recalls are done voluntarily.

Section 810.10(d)—FDA estimates that it will take approximately 8 hours for the person named in a cease distribution and notification order to gather and submit the information required by this section.

The total estimated annual burden is 16 hours.

Section 810.11(a)—Based on experience in similar situations, FDA expects that there will be only one request for a regulatory hearing per year and that it will take approximately 8 hours to prepare this request.

Section 810.12(a) and (b)—Based on experience in similar situations, FDA expects that there will be only one written request for a review of a cease distribution and notification order per year and that it will take approximately 8 hours to prepare this request.

Section 810.14—Based upon its experience with voluntary recalls, FDA estimates that it will take approximately 16 hours to develop a strategy for complying with the order.

Section 810.15(a) through (d)—Based upon its experience with voluntary recalls, FDA estimates that it will take approximately 16 hours to notify each health professional, user facility, or individual of the order.

Section 810.15(e)—Based upon its experience with voluntary recalls, FDA estimates that there will be approximately five consignees per recall (10 per year) who will be required to notify their consignees of the order. FDA estimates that it will take them about 1 hour to do so.

Section 810.16—FDA estimates that it would take no more than 40 hours to assemble and prepare a written status report required by a recall. The status reports are prepared by manufacturers

six to twelve times each year. Therefore, each manufacturer would spend no more than 480 hours each year preparing status reports. If there were two FDA invoked recalls each year, the total burden hours estimated would be 960 hours each year.

Section 810.17—Based on experience with similar procedures, FDA estimates that it would take 8 hours to draft a written request for termination of a cease distribution and notification or mandatory recall order.

Dated: November 23, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-23519 Filed 11-30-05; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005D-0438]

#### **Draft Guidance for Industry on Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency; 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: Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency," dated November 2005. The draft guidance document provides recommendations for testing the safety, efficacy, and pharmacokinetics of immune globulin

intravenous (human) (IGIV) products as replacement therapy in primary humoral immunodeficiency. The draft guidance document is intended to assist sponsors with the design of clinical trials to assess IGIV as replacement therapy in primary humoral immunodeficiency.

**DATES:** Submit written or electronic comments on the draft guidance by March 1, 2006, to ensure their adequate consideration in the preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. 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 the Center for Biologics Evaluation and Research at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Paula S. McKeever, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

#### **I. Background**

FDA is announcing the availability of a draft document entitled "Guidance for

Industry: Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency," dated November 2005. IGIV products are prepared from large pools of plasma collected from large numbers of individual healthy donors, and therefore contain antibodies against many bacterial, viral, and other infectious agents. This draft guidance provides recommendations for the design of clinical trials to assess the safety and efficacy of IGIV products when used as replacement therapy in primary humoral immunodeficiency. The draft guidance is intended to assist in the preparation of the clinical/ biostatistical and human pharmacokinetic sections of the biologics license application (BLA).

This draft guidance does not address additional sections of a BLA for an IGIV product for this indication, such as chemistry, manufacturing, and controls (CMC), and preclinical toxicology.

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 the 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 requirement of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions 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 collection(s) of information in the guidance was approved under OMB control number 0910-0338.

## III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of

Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: November 17, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-23520 Filed 11-30-05; 8:45 am]

**BILLING CODE 4160-01-S**

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## INTERNATIONAL TRADE COMMISSION

[USITC SE-05-044]

### Sunshine Act Meeting

**AGENCY HOLDING THE MEETING:** United States International Trade Commission.

**TIME AND DATE:** December 7, 2005 at 11 a.m.

**PLACE:** Room 101, 500 E Street, SW., Washington, DC 20436, Telephone: (202) 205-2000.

**STATUS:** Open to the public.

**MATTERS TO BE CONSIDERED:**

1. Agenda for future meetings: None.
2. Minutes.
3. Ratification List.
4. Inv. No. 731-TA-1098

(Preliminary) (Liquid Sulfur Dioxide from Canada)—briefing and vote. (The Commission is currently scheduled to transmit its determination to the Secretary of Commerce on or before December 8, 2005; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on or before December 15, 2005.)

5. Inv. Nos. 731-TA-639 and 640 (Second Review) (Forged Stainless Steel Flanges from India and Taiwan)—briefing and vote. (The Commission is currently scheduled to transmit its determination and Commissioners' opinions to the Secretary of Commerce on or before December 16, 2005.)

6. *Outstanding action jackets:* None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: November 29, 2005.

**Marilyn R. Abbott,**

*Secretary to the Commission.*

[FR Doc. 05-23574 Filed 11-29-05; 2:43 pm]

**BILLING CODE 7020-02-P**

## INTERNATIONAL TRADE COMMISSION

[USITC SE-05-043]

### Sunshine Act Meeting

**AGENCY HOLDING THE MEETING:** United States International Trade Commission.

**TIME AND DATE:** December 5, 2005 at 2 p.m.

**PLACE:** Room 101, 500 E Street, SW., Washington, DC 20436, Telephone: (202) 205-2000.

**STATUS:** Open to the public.

**MATTERS TO BE CONSIDERED:**

1. Agenda for future meetings: None.
2. Minutes.
3. Ratification List.
4. Inv. No. 731-TA-1090 (Final)

(Superalloy Degassed Chromium from Japan)—briefing and vote. (The Commission is currently scheduled to transmit its determination and Commissioners' opinions to the Secretary of Commerce on or before December 15, 2005.)

5. *Outstanding action jackets:* None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: November 28, 2005.

**Marilyn R. Abbott,**

*Secretary to the Commission.*

[FR Doc. 05-23575 Filed 11-29-05; 2:43 pm]

**BILLING CODE 7020-02-P**

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## DEPARTMENT OF JUSTICE

### Notice of Lodging of Amended Consent Decree Under the Comprehensive Environmental Response, Compensation and Liability Act

In accordance with 28 CFR 50.7 and Section 122 of the Comprehensive Response, Compensation and Liability Act ("CERCLA"), 42 U.S.C. 9622, the Department of justice gives notice that on November 4, 2005, a proposed revised consent decree in *United States v. DeMert & Dougherty, Inc.*, No. 2:02CV434 (N.D. Ind.), was lodged with the United States District Court for the Northern District of Indiana.

The United States' complaint seeks the recovery, pursuant to CERCLA Section 107, 42 U.S.C. 9607, of unreimbursed costs that have been incurred by the United States at the American Chemical Service, Inc. Superfund Site in Griffith, Lake County, Indiana ("ACS Site"), as well as well as