

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 This draft guidance provides recommendations for the design of clinical trials to assess the safety and efficacy of IGIV products when used as replacement therapy in primary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 The draft guidance is intended to assist in the preparation of the clinical/ biostatistical and human pharmacokinetic sections of the biologics license application (BLA).

This draft guidance does not address additional sections of a BLA for an IGIV product for this indication, such as chemistry, manufacturing, and controls (CMC), and preclinical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The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the FDA's current thinking on this topic.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The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time.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may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance.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 A copy of the draft guidance and received comments are available for public examination in the Division of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

the implementation, pursuant to CERCLA Section 106, 42 U.S.C. 9606, of the United States Environmental Protection Agency's selected remedy for the ACS Site.

On January 11, 1996, DeMert & Dougherty, Inc., filed for bankruptcy under Chapter 11 of the bankruptcy Code in the U.S. District Court for the Northern District of Illinois. (*In re: DeMert & Dougherty, Inc.* (Bankr. N.D. 11. (Eastern Div. No. 96 B 0851))). The case was converted to a Chapter 7 Bankruptcy on June 27, 1996. In that case, the United States filed a proof of claim pertaining to the costs that it incurred at the ACS Site.

A consent decree lodged in 2002 would have resolved DeMert's liability as to the site and the United States' claim in DeMert's bankruptcy through the allowance of an allowed general unsecured claim of \$2,225,000.<sup>1</sup>

Public Comments received by the Department of Justice from the group performing the remedy at the ACS Site ("ACS Group") necessitated the withdrawal of the first consent decree and additional negotiations, which resulted in the proposed revised consent decree. The proposed revised decree would resolve DeMert's liability at the ACS Site under CERCLA and resolve the competing claims of the United States and the ACS Group in DeMert's bankruptcy action, as well as the claims that the ACS Group and DeMert may have against each other. In particular: (1) The ACS Group's claim in DeMert's bankruptcy would be allowed as a general unsecured claim for \$2,225,000, while the United States bankruptcy claim would be deemed to have been withdrawn; one-half of the total amount paid to the ACS Group in the bankruptcy would be deposited in an account within the Superfund and be available to reimburse the ACS Group's Operation and Maintenance costs at the Site; the remainder of the amount paid through the bankruptcy would be deposited in a different account within the Superfund for use by EPA in conducting or financing response actions connected with the ACS Site, or for use at other Sites; (2) the Trustee will assist the ACS Group in litigation resulting from actions taken by the ACS Group to obtain coverage under DeMert's insurance policies; (3) DeMert assigns to the ACS Group DeMert's rights to receive payments under

DeMert's insurance policies for the Site, and the Trustee will assist the ACS Group in litigation resulting from the ACS Group's attempts to obtain coverage under DeMert's insurance policies. The ACS Group would reimburse the Trustee for the fees and expenses incurred in assisting the ACS Group in such litigation.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611, and should refer to *United States v. Dougherty, Inc.*, D.J. Ref. 90-11-3-1094.

The Consent Decree may be examined at the Office of the United States Attorney, Northern District of Indiana, 5400 Federal Plaza, Suite 1500, Hammond, Indiana 44320 (contact Assistant United States Attorney Wayne Ault, 219-937-5500), and at U.S. EPA Region 5, 77 W. Jackson Blvd., Chicago, Illinois (contact Assistant Regional Counsel Michael McClary (312-886-7163)). During the public comment period, the proposed Amended Consent Decree may also be examined on the following Department of Justice Web site, <http://www.usdoj.gov/enrd/open.html>. A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611, or by faxing a request to Tonia Fleetwood, fax no. (202) 616-6583, phone confirmation number (202) 514-1547. In requesting a copy, please refer to the referenced case and enclose a check in the amount of \$18.00 (25 cents per page reproduction costs) payable to the U.S. Treasury.

**William Brighton,**

*Assistant Chief, Environmental, Enforcement Section, Environment and Natural Resources Division.*

[FR Doc. 05-23508 Filed 11-30-05 8:45 am]

**BILLING CODE 4410-15-M**

**NATIONAL INSTITUTE FOR LITERACY**

**National Institute for Literacy Advisory Board; Sunshine Act Meeting**

**AGENCY:** National Institute for Literacy.

**ACTION:** Notice of closed meeting.

**SUMMARY:** This notice sets forth the schedule and a summary of the agenda for an upcoming meeting of the National Institute for Literacy Advisory Board (Board). The notice also describes the

functions of the Board. Notice of this meeting is required by section 10(a)(2) of the Federal Advisory Committee Act.

**DATE AND TIME:** Closed session—December 12, 2005 from 2 p.m. to 4 p.m.

**ADDRESSES:** National Institute for Literacy, 1775 I Street, NW., Suite 730, Washington, DC 20006.

**FOR FURTHER INFORMATION CONTACT:** Liz Hollis, Special Assistant to the Director; National Institute for Literacy, 1775 I Street, NW., Suite 730, Washington, DC 20006; telephone number: (202) 233-2072; e-mail: [ehollis@nifl.gov](mailto:ehollis@nifl.gov).

**SUPPLEMENTARY INFORMATION:** The Board is established under section 242 of the Workforce Investment Act of 1998, Public Law 105-220 (20 U.S.C. 9252). The Board consists of ten individuals appointed by the President with the advice and consent of the Senate. The Board advises and makes recommendations to the Interagency Group. The Interagency Group is composed of the Secretaries of Education, Labor, and Health and Human Services, and the three Secretaries administer the National Institute for Literacy (Institute). The Interagency Group considers the Board's recommendations in planning the goals of the Institute and in implementing any programs to achieve those goals. Specifically, the Board performs the following functions: (a) Makes recommendations concerning the appointment of the Director and the staff of the Institute; (b) provides independent advice on operation of the Institute; and (c) receives reports from the Interagency Group and the Institute's Director.

The National Institute for Literacy Advisory Board meeting on December 12, 2005 from 2 p.m. to 4 p.m. will be closed to the public to discuss the personnel, staffing and performance issues. This discussion relates to the internal personnel rules and practices of the Institute and is likely to disclose information of personal nature where disclosure would constitute a clearly unwarranted invasion of personnel privacy. The discussion must therefore be held in closed session under exemptions 2 and 6 of the Government in the Sunshine Act, 5 U.S.C. 552b(c)(2) and (6). Due to administrative issues associated with scheduling, this announcement will be published in the **Federal Register** less than 15 days prior to the date of the meeting. A summary of the activities at the closed session and related matters that are informative to the public and consistent with the policy of 5 U.S.C. 552b will be available to the public within 14 days of the meeting. Records are kept of all

<sup>1</sup> DeMert filed for bankruptcy under Chapter 11 of the Bankruptcy Code in the U.S. District Court for the Northern District of Illinois in 1996, and the case was later converted to a Chapter 7 Bankruptcy. (*In re: DeMert & Dougherty, Inc.* (Bankr. N.D. 11. (Eastern Div. No. 96B90851))). Both the United States and the ACS Group filed proofs of claim.