

1. **LOT:** A lot is a quantity of casein, caseinates, or mixtures thereof packaged by one manufacturer during a definite period of time not exceeding one (1) week. The manufacturing process, including milling and packaging, is performed by using a perfectly identified processing line. Caseins, caseinates, or mixtures thereof intended for export to the United States are packaged, after milling, in identical containers identified by a unique code or mark traceable to the manufacturer.
2. **SALMONELLA-NEGATIVE:** The absence of *Salmonella* in thirty (30) subsamples, each of twenty-five (25) grams, that have been taken from bags in the same lot of product immediately before closing and tested using the procedures contained in the current edition of the "Bacteriological Analytical Manual." The Bacteriological Analytical Manual can be accessed at <http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm>.
3. **PHOSPHATASE-NEGATIVE:** The absence of phosphatase activity in thirty (30) subsamples, each of twenty-five (25) grams, that have been taken from bags in the same lot of product immediately before closing and tested using the method contained in the current edition of the "Official Methods of Analysis." This method may be obtained from the AOAC International, 481 North Frederick Avenue, Suite 500, Gaithersburg, Maryland 20877 USA, telephone +1 301-924-7077, fax +1 301-924-7089, email [aoac@aoac.org](mailto:aoac@aoac.org) and website [www.aoac.org](http://www.aoac.org).

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

#### Risk Mitigation Strategies To Address Potential Procoagulant Activity in Immune Globulin Intravenous Products; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA), in cooperation with the National Heart, Lung, and Blood Institute, and the Plasma Protein Therapeutics Association, are jointly cosponsoring a public workshop on risk mitigation strategies to address procoagulant activity that may be present in some Immune Globulin Intravenous (IGIV) products. The purposes of the public workshop are to identify the most likely causes of IGIV-associated thrombotic events, to determine which procoagulant proteins may be causative, and to identify relevant, feasible tests that could be used to assess levels and/or activity of these proteins in IGIV products. The public workshop will feature presentations by national and international experts from government, academic institutions, and industry.

**Dates and Time:** The public workshop will be held on May 17, 2011, from 8:30

a.m. to 5 p.m. and May 18, 2011, from 8 a.m. to 11:30 a.m.

**Location:** The public workshop will be held at the Universities at Shady Grove Conference Center, Building II, Multipurpose Room, 9630 Gudelsky Dr., Rockville, MD 20850. Please visit <http://www.shadygrove.umd.edu/about/visit> for directions, visitor parking, and public transportation information.

**Contact Person:** Rhonda Dawson, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6129, FAX: 301-827-2843, e-mail: [rhonda.dawson@fda.hhs.gov](mailto:rhonda.dawson@fda.hhs.gov).

**Registration:** Mail or fax your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by April 26, 2011. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson at least 7 days in advance of the workshop.

**SUPPLEMENTARY INFORMATION:** The following topics will be discussed at the public workshop: (1) Epidemiology of thrombotic events in IGIV recipients; (2) pathophysiology of arterial and venous thrombosis in this context; (3) research to identify specific procoagulant proteins that can co-purify with IGIV; (4) partitioning of coagulation factors during IGIV purification; (5) the role of

activated Coagulation Factor XIa in IGIV-associated thrombosis; (6) test methods for screening IGIV products; (7) ancillary animal models; and (8) standards development for thrombin generation tests. On the first day of the public workshop, the epidemiology and potential causes of historically observed IGIV-associated thrombotic adverse events, as well as biochemical identification of procoagulant proteins that co-purify with IGIV will be discussed. In addition, methods and relevance of both broad and specific tests to screen IGIV products for procoagulant activity will be addressed, and limitations in test methodologies and validation needs will be identified. On the second day of the public workshop, preliminary results of IGIV product testing for procoagulant activity will be presented and discussed, followed by a summary of the meeting.

**Transcripts:** Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm>.

Dated: March 10, 2011.

**Leslie Kux,**

Acting Assistant Commissioner for Policy.

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