evaluation of these drugs to WHO, through the Secretary of State, for WHO's consideration in deciding whether to recommend international control/decontrol of any of these drugs. Such control could limit, among other things, the manufacture and distribution (import/export) of these drugs and could impose certain recordkeeping requirements on them.

HHS will not now make any recommendations to WHO regarding whether any of these drugs should be subjected to international controls. Instead, HHS will defer such consideration until WHO has made official recommendations to the Commission on Narcotic Drugs, which are expected to be made in early 2015. Any HHS position regarding international control of these drugs will be preceded by another **Federal Register** notice soliciting public comments, as required by section 201(d)(2)(B) of the CSA.

IV. Comments

Interested persons may submit either electronic comments regarding the drugs to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**) by January 29, 2014. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this notice. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Dated: December 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–31212 Filed 12–27–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Strategies To Address Hemolytic Complications of Immune Globulin Infusions; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Strategies to Address Hemolytic Complications of Immune Globulin Infusions.'' The purpose of the public workshop is to identify and discuss potential risk mitigation strategies for Immune Globulin (Ig)-associated hemolysis and to identify and discuss important research questions related to patient risk and product characteristics. The workshop has been planned in partnership with the National Heart, Lung, and Blood Institute, National Institutes of Health, and the Plasma Protein Therapeutics Association. The workshop will include presentations and panel discussions by experts from academic institutions, industry, and government agencies.

Dates and Times: The public workshop will be held on January 28, 2014, 8:30 a.m. to 5 p.m. and January 29, 2014, 8:30 a.m. to 12 noon.

Location: The public workshop will be held at Lister Hill Center Auditorium, National Institutes of Health Campus, Building 38A, 8600 Rockville Pike, Bethesda, MD 20894.

Contact Person: Chris Nguyen, Center for Biologics Evaluation and Research (HFM–49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2000, FAX: 301–827–3079, email: *CBERPublicEvents@fda.hhs.gov*.

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, and fax numbers) to Chris Nguyen (see Contact Person) or email to *CBERPublicEvents@fda.hhs.gov* (subject line: IG Hemolysis Workshop Registration) by January 10, 2014. 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. Pre-registered participants will receive additional information on security procedures, parking, and public transportation with their email registration confirmation.

If you need special accommodations due to a disability, please contact Chris Nguyen (see Contact Person) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Clinically significant hemolysis is a long-recognized complication of Immune Globulin Intravenous (IGIV) (Human) infusion. Complications of hemolysis include severe anemia requiring transfusion, renal failure, and disseminated intravascular coagulation. Ig-associated hemolysis has been generally thought to be caused by the presence of Immunoglobulin G (IgG) antibodies against major red blood cell antigens. All FDA-licensed Ig products are tested and have upper limit release specifications for antibodies against blood group antigens A, B, and Rho(D). However, IGIV-associated hemolysis occurs despite adherence to these specifications. In addition, there are factors that may increase a patient's risk for hemolysis. Known patient risk factors for hemolysis include: (1) High doses of IGIV; (2) recipient blood type A, AB, or B; and (3) other factors, such as history of hemolysis and possibly underlying inflammatory disease.

The goals of the workshop are to identify and discuss potential risk mitigation strategies for Ig-associated hemolysis, including improved identification of patients at high risk for hemolysis; changes in product specifications, tests, or test methods; and modifications to manufacturing to lower product risk. In addition, this workshop is intended to identify and discuss important outstanding research questions related to patient risk and product characteristics.

The first day of this workshop will include presentations and panel discussions on the following topics: (1) Pathogenesis and epidemiology of IGIV-associated hemolysis; (2) patient risk factors; and (3) possible product risk factors, including the presence of Anti-A and Anti-B hemagglutinins.

The second day of the workshop will include presentations and panel discussions on the following topics: (1) Immune globulin manufacturing and risk mitigation strategies and (2) workshop summary and conclusions.

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at: *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm.* Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857.

Dated: December 23, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–31213 Filed 12–27–13; 8:45 am]

BILLING CODE 4160–01–P