TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
101.105(t); recordkeeping pertaining to disclosure requirements for food not accurately labeled for quantity of contents	100	1	100	1	100
Total					676,150

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section/Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
101.9(j)(18) and 101.36(h)(2); procedure for small business nutrition labeling exemption notice using Form FDA 3570	10,000	1	10,000	8	80,000
101.12(h); petitions to establish or amend a RACC	5	1	5	80	400
101.69; petitions for nutrient content claims	3	1	3	25	75
101.70; petitions for health claims	5	1	5	80	400
101.108; written proposal for requesting temporary exemptions from certain regulations for the purpose of conducting food labeling experiments	1	1	1	40	40
Total					80,915

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated annual third-party disclosure, recordkeeping, and reporting burdens are based on our communications with industry and our knowledge of and experience with food labeling and the submission of petitions and requests to us.

As noted, we are revising this collection to include previously approved third-party disclosure burdens associated with the requirement to declare the amount of *trans* fatty acids present in a food, including dietary supplements. The third-party disclosure burden hours formerly associated with OMB control number 0910–0515 (collection entitled, ''Food Labeling: Trans Fatty Acids in Nutrition Labeling'') are represented by the citation to § 101.9 on line 4 of table 1 and the citation to § 101.36 on line 17 of table 1. For this revision, we have not added burden hours to line 4 or line 17 of table 1 because, based on our experience with food labeling, the 4 hours estimated for meeting the labeling requirements of § 101.9 and the 4 hours estimated for meeting the labeling requirements of § 101.36 are appropriate estimates of the total time it takes a respondent to meet our requirements for nutrition labeling in §§ 101.9 and 101.36.

We are also revising this collection to include previously approved third-party disclosure burdens associated with the voluntary declaration of the quantitative amount and the percent of Daily Value of a dietary ingredient on a ''per day'' basis in addition to the required ''per serving'' basis. The third-party disclosure burden hours formerly associated with OMB control number 0910–0395 (collection entitled, ''Food Labeling: Nutrition Labeling of Dietary Supplements on a 'Per Day' Basis'') are represented by the citation to § 101.36 on line 17 of Table 1 and the addition of 300 hours to our previous estimate of 48,000 hours. For this revision, we added 300 burden hours to line 17 of table 1 because voluntary labeling on a ''per day'' basis is in addition to the required ''per serving'' basis. We estimate that ''per day'' information would generally be placed on, at most, 10 percent of the estimated 12,000 disclosures, for a total of 1,200 annual disclosures, and that a respondent will spend 15 minutes (0.25 hours) per disclosure, for a total of 300 hours. Thus, the total estimated burden on line 17 of table 1 is 48,300 hours and average burden per disclosure on line 17 of table 1 has been increased from 4.0 to 4.025 hours, to represent an averaging of the burden hours across all of the estimated 12,000 disclosures.

We expect that the burden hours for submissions under § 101.108 will be insignificant. Section 101.108 was originally issued to provide a procedure whereby we could grant exemptions from certain food labeling requirements. Exemption petitions have infrequently been submitted in the recent past; none have been submitted since publication on January 6, 1993, of the final regulations implementing section 403(q) and (r) of the FD&C Act. Thus, in order to maintain OMB approval of § 101.108 to accommodate the possibility that a food producer may propose to conduct a labeling experiment on its own initiative, we estimate that we will receive one or fewer submissions under § 101.108 in the next 3 years.

Dated: December 23, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–31215 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–1676]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Tapentadol; Tramadol; Ketamine; gamma-Butyrolactone; 22 Additional Substances; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting

interested persons to submit comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of 26 drug substances. These comments will be considered in preparing a response from the United States to the World Health Organization (WHO) regarding the abuse liability and diversion of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drugs. This notice requesting comments is required by the Controlled Substances Act (CSA).

DATES: Submit written or electronic comments by January 29, 2014.

ADDRESSES: Submit written comments 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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: James R. Hunter, Center for Drug Evaluation and Research, Controlled Substance Staff, Food and Drug Administration, Bldg. 51, Rm. 5150, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3156, email: *james.hunter@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The United States is a party to the 1971 Convention on Psychotropic Substances. Article 2 of the Convention on Psychotropic Substances provides that if a party to the convention or WHO has information about a substance, which in its opinion may require international control or change in such control, it shall so notify the Secretary General of the United Nations and provide the Secretary General of the United Nations with information in support of its opinion.

Section 201 of the CSA (21 U.S.C. 801 et seq.) (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970) provides that when WHO notifies the United States under Article 2 of the Convention on Psychotropic Substances that it has information that may justify adding a drug or other substances to one of the schedules of the convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State must transmit the notice to the Secretary of Health and Human Services (the Secretary of HHS). The Secretary of HHS must then publish the notice in the **Federal Register** and provide opportunity for interested persons to submit comments that will be considered by HHS in its preparation of the scientific and medical evaluations of the drug or substance.

I. WHO Notification

The Secretary of HHS received the following notices from WHO:

Ref.: C.L.29.2013

The World Health Organization (WHO) presents its compliments to Member States and Associate Members and has the pleasure of informing that the Thirty-sixth Expert Committee on Drug Dependence (ECDD) will meet in June 2014 to review a number of substances with potential for misuse in order to make recommendations to the Director-General, on the need for and level of international control of these substances.

At its 126th session in January 2010, the Executive Board approved the publication ''Guidance on the WHO review of psychoactive substances for international control'' (EB126/2010/REC1, Annex 6) which requires the Secretariat to request relevant information from Ministers of Health in Member States to prepare a report for submission to the ECDD. For this purpose, a questionnaire was designed to gather information on the legitimate use, harmful use, status of national control and potential impact of international control for each substance under evaluation. Member States are invited to collaborate, as in the past, in this process by providing pertinent information mentioned in the questionnaire concerning substances under review.

It would be appreciated if a person from the Ministry of Health could be designated as the focal point responsible for coordinating and answering the questionnaire. It is requested that the email address of the focal point be shared with the Secretariat * * *. Upon receipt of the email of the designated person, the focal point will receive a unique user name, password and link for accessing the questionnaire and responding to questions. Further instructions on answering the questionnaire will be provided, along with the questionnaire, online. Further clarification on the above items can be obtained from the Secretariat by emailing: *ecdd_secretariat@who.int*. Replies to the questionnaire must reach the Secretariat by 1 February 2014 in order to facilitate analyses and preparation of the report before the planned meeting. Where there is a Competent National Authority under the International Drug Control Treaties, it is kindly requested that the questionnaire be completed in collaboration with such body. The summary information from the questionnaire will be published online as part of the report at the Web site for the Thirty-sixth ECDD linked to the Department of Essential Medicines and Health Products (EMP): *http://www.who.int/medicines/areas/quality_safety/ECDD/en/index.html*.

The World Health Organization takes this opportunity to renew to Member States and Associate Members the assurance of its highest consideration.

GENEVA, 11 November 2013

* * * * *

ENCL.: (1)

Substances Identified for Evaluation During the 36th Expert Committee on Drug Dependence

Tapentadol
N-benzylpiperazine (BZP)
Gamma-Butyrolactone (GBL)
1,4-Butanediol (I,4BD)
Synthetic cannabinoids
- JWH–018
- JWH–073
- AM–2201
- UR–144
- APINACA (AKB 48)
- RCS–4
- JWH–250

Synthetic Cathinones
- Mephedrone 4-methylmethcathinone (4–MMC)
- 3,4-Methylenedioxypyrovalerone (MDPV)
- Methylone (bk-MDMA)
- 4-Methylethcathinone (4–MEC)
- 4-Fluoromethcathinone (flephedrone; 4–FMC)

Miscellaneous
- 25 B NBOMe
- 25 C NBOMe
- 25 I NBOMe
- Alpha-methyltryptamine (AMT)
- AH–7921
- Methoxetamine (MXE)
- Methiopropamine (MPA)

Lisdexamphetamine
Tramadol
Ketamine

* * * * *

WHO Questionnaire for the 36th Meeting of Expert Committee on Drug Dependence: Substance

Definitions:

(Def. 1) Legitimate use is use of a substance for legally valid purposes such as medical scientific and industrial.

(Def. 2) Harmful use is defined as a pattern of psychoactive substance use that increases the risk of harmful physical, mental, and social consequences for the user or to others. Harmful use of drugs by an individual has potential for adverse effects on the substance user's family, the community and society in general.

Substance* (Insert name of substance)

—Do you have any information on this substance on legitimate use, recreational/harmful use or control status in your country? * (Yes/No)

A. LEGITIMATE MEDICAL OR OTHER SCIENTIFIC USE OF THE SUBSTANCE (Def. 1)

—Is the substance currently authorized or in the process of being authorized/registered as a medical product in your country? (Yes/No)

If ''yes,'' since when has it been on the market? (input year)

—Please state registered indications for this medicine:

—Please mention other, if any, medical use not included in the approved indications (off label use):

—Please indicate dosage form(s) and strength(s) available in your country; also

indicate special properties such as slow release, etc.:

	Dosage form	Strength	Remarks
1.			
2.			
3.			

—Please list alphabetically the brand names available in your country (there is no need for dosage forms, strengths, etc.):
—Are there any other uses for the substance in health care (such as for diagnostic tests) in your country? (Yes/No)
If ''yes,'' what is the use?
—Is the chemical used for medical or scientific research in your country? (Yes/No)
If ''yes,'' please specify:
—Is the substance used for animal care (veterinary use)? (Yes/No)
—Is there any other legitimate (Def. 1) use of the substance (e.g. industry uses)? (Yes/No)
If ''yes,'' please state the purpose:
—If there is any legitimate (Def. 1) use of the substance, how is the substance sourced? (Manufactured in country/Imported)
—What is the estimated approximate amount needed for its legitimate use in your country per year?
—Is the substance used for cultural or ceremonial purposes? (Yes/No)
If ''yes,'' specify why it is used:
Who uses it (the group using)?
How is it used? (route of administration):
What is its source?

B. HARMFUL USE OF THE SUBSTANCE (Def. 2)

—Is there recreational/harmful use of this substance in your country? (Def. 2) (Yes/No/Unknown)
If ''yes,'' please specify how the substance is used and the extent of use by answering the following questions:
Common route(s) of administration (Oral/Injection/Inhaling or sniffing)
How is it obtained? (Diversion/Trafficking/Clandestine manufacturing)
Common formulation(s) available: (Powder/Tablet/Liquid)
—Any other information on recreational/harmful use:
—Quantity of substance used by an average misuse per sitting (average dose used):
—Is it used by special population(s)? (Club use/General population)

	Club use (percent)	General population (percent)
Estimated proportion of the population using the substance		

—Please provide any information on the extent/magnitude of public health or social harm from the use of the substance (Def. 2) in your country:

	Overdose deaths reported	Addiction programme enrolment from the use of this substance	Emergency room visits resulting from the use of this substance	Dependence to this substance
Numbers in 2012				

—Are there reports of withdrawal, tolerance, other adverse effects or medical illnesses caused by this substance in your country? (Yes/No)
If ''yes,'' please provide details:
—Any other relevant information on harm to individuals or the society:
—Please indicate the sources of information on harm:
—If actual data are not available, please provide a short description on harm caused by this substance:

C. CONTROL OF THE SUBSTANCE

—Is the substance controlled under legislation that is intended to regulate its availability in the country? (Yes/No)
If ''yes,'' please select which one: (Controlled substances act/Medicines law/Poisons acts/Consumer protection acts/Generic legislation/Analogue legislation/Temporary ban/Other legislation (name))
—How is this law enforced? Please provide a short description:
—Are there challenges to implementation? (Yes/No)
If ''yes,'' please specify (e.g. laboratory capacity, resources to implement and/or enforce, expertise):
—Are there illicit activities involving the substance? (Yes/No)
Clandestine manufacture? (Yes/No)
The manufacture (synthesis) of the chemical itself (Yes/No)
The processing into the consumer product, i.e. adding it to herbal material, packaging (Yes/No)
Trafficking (Yes/No)
Diversion (Yes/No)
Internet market (Yes/No)
Other (please specify):
—Please provide any other relevant information on illicit activities:
—Data on seizures

Year	Number of seizures	Kilograms	Litres	Number of ampoules	Number of tablets/pills	Other type (quantity)
2011						
2012						

D. IMPACT OF SCHEDULING

—If this substance is placed under international control, does your country have the lab capacity to identify the substance? (Yes/No/Unknown)
—If this substance is placed under international control, do you think its availability for medical use will be affected? (Yes/No)
If ''yes,'' please explain (consider both human and veterinary needs): How could control impact its medical availability? Please identify specific population groups that may be affected, and describe the implications of increased control.
—Any additional information on impact of scheduling:

* * * * *

II. Background

Tapentadol is a central nervous system active analgesic agent that has mu (μ) opioid agonist properties and inhibits the reuptake of norepinephrine. Tapentadol is approved for marketing in the United States for the treatment of moderate to severe acute pain.

Tapentadol is controlled in Schedule II under the CSA in the United States. Tapentadol was pre-reviewed by the WHO Expert Committee on Drug Dependence at its 35th meeting and recommended for critical review at its 36th meeting.

N-benzylpiperazine (BZP) is used as an intermediate in chemical synthesis but has been taken orally as either powder or tablets and by other routes, including smoking or snorting. It has no medical use in the United States. BZP is controlled in Schedule I under the CSA in the United States. BZP is not controlled internationally under the Convention on Psychotropic Substances or the Single Convention on Narcotic Drugs. BZP was pre-reviewed by the WHO Expert Committee on Drug Dependence at its 35th meeting and recommended for critical review at its 36th meeting.

Gamma-Butyrolactone (GBL) is used as an industrial solvent. GBL can be converted in the body to the central nervous system depressant drug gamma-hydroxybutyric acid (GHB). GBL is controlled as a List I chemical in the United States under the CSA. It is not controlled internationally under the Convention on Psychotropic Substances or the Single Convention on Narcotic Drugs. GBL was pre-reviewed by the WHO Expert Committee on Drug Dependence at its 35th meeting and recommended for critical review at its 36th meeting.

1,4-Butanediol is used as an industrial solvent for manufacturing and also used for the synthesis of GBL. 1,4-Butanediol can also be converted to the central nervous depressant drug GHB. It has no medical use in the United States. 1,4-Butanediol is not controlled under the CSA in the United States, but it is subject to controls in several states under state law. 1,4-Butanediol was pre-reviewed by the WHO Expert Committee on Drug Dependence at its 35th meeting and recommended for critical review at its 36th meeting.

The following substances are classified as synthetic cannabinoids with pharmacological properties like tetrahydrocannabinol: (1-pentyl-1H-indol-3-yl)-1-naphthalenyl-methanone (JWH–018), (1-butyl-1H-indol-3-yl)-1-naphthalenyl-methanone (JWH–073), 1-(1-pentyl-1H-indol-3-yl)-2-(2-methoxyphenyl)-ethanone (JWH–250), [1-(5-fluoropentyl)-1H-indol-3-yl]-1-naphthalenyl-methanone (AM–2201), (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)-methanone (UR–144), 1-pentyl-N-tricyclo[3.3.1.13,7]dec-l-yl-1H-indazole-3-carboxamide (APINACA; AKB48), and (4-methoxyphenyl)(1-pentyl-1H-indol-3-yl)methanone (RCS–4). JWH–018, JWH–073, JWH–250, AM–2201, and RCS–4 are controlled in Schedule I under the CSA in the United States. On May 16, 2013, UR–144 and AKB 48 were temporarily placed in Schedule I under the CSA pursuant to the temporary scheduling provisions of section 201(h) of the CSA (21 U.S.C. 811(h)).

4-Methylmethcathinone (4–MMC; mephedrone), 3,4-methylenedioxypyrovalerone (MDPV), 3,4-methylenedioxy-N-methylcathinone (bk-MDMA; Methylone), 4-methylethcathinone (4–MEC), and 4-fluoromethcathinone (flephedrone; 4–FMC) are classified as synthetic cathinones in the phenethylamine class and are structurally and pharmacologically similar to amphetamine, 3,4-methylenedioxymethamphetamine (MDMA), cathinone and other related substances. 4–MMC, MDPV, and Methylone are controlled in Schedule I under the CSA in the United States. 4–MEC and 4–FMC are not controlled under the CSA in the United States.

2-(4-bromo-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine (25B–NBOMe), 2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C–NBOMe), and 2-(4-iodo-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine (25I–NBOMe) are synthetic 2C phenethylamine substances and were developed for use in mapping and investigating the serotonin receptors in the mammalian brain. On November 15, 2013, 25B–NBOMe, 25C–NBOMe, and 25I–NBOMe were temporarily placed in Schedule I of the CSA pursuant to the temporary scheduling provision of section 201(h) of the CSA.

Alpha-Methyltryptamine (AMT) is a tryptamine (indoleethylamine) derivative and shares several similarities with the Schedule I tryptamine hallucinogens, such as alpha-ethyltryptamine (AET) and N,N-dimethyltryptamine (DMT). AMT is controlled in Schedule I under the CSA in the United States.

AH–7921, or 1-(3,4-dichlorobenzamidomethyl) cyclohexyldimethylamine, is an opioid analgesic drug selective for the μ-opioid receptor and is not controlled under the CSA in the United States.

Methoxetamine (MXE), or 2-(ethylamino)-2-(3-methoxyphenyl)-cyclohexanone, is an arylcyclohexamine and is not controlled under the CSA in the United States. MXE can be considered as a controlled substance analogue of eticyclidine (PCE) under the CSA if intended for human consumption.

Methiopropamine (MPA) is a thiophene analog of methamphetamine and is not controlled under the CSA in the United States.

Lisdexamphetamine is an amide ester conjugate comprised of the amino acid L-lysine covalently bound to the amino group of d-amphetamine. Lisdexamphetamine was approved for marketing in the United States in 2007 and is used for the treatment of Attention Deficit Hyperactivity Disorder. Lisdexamphetamine was placed in Schedule II of the CSA in June 2007.

Tramadol is an opioid analgesic that produces its primary opioid-like action through an active metabolite referred to as the M1 metabolite·(O-desmethyltramadol). Tramadol was first approved for marketing in the United States in 1995 and is available in immediate-release, extended-release, and combination product for the treatment of moderate to moderately-severe pain. In November 2013, Tramadol was proposed to be placed in Schedule IV of the CSA. The Secretariat indicates that additional safety information on this substance is available, thus an updated review for Tramadol is necessary for presentation at the 36th meeting of the WHO Expert Committee on Drug Dependence.

Ketamine is classified as a rapid-acting general anesthetic agent used for short diagnostic and surgical procedures that do not require skeletal muscle relaxation. It is marketed in the United States as an injectable. Ketamine is controlled in Schedule III of the CSA in the United States. It is not controlled internationally under the Convention on Psychotropic Substances or the Single Convention on Narcotic Drugs. The WHO Expert Committee on Drug Dependence reviewed ketamine at its 34th and 35th meetings. The Secretariat indicates that additional safety information on this substance is available, thus an updated review for ketamine is necessary for presentation at the 36th meeting of the WHO Expert Committee on Drug Dependence.

III. Opportunity To Submit Domestic Information

As required by section 201(d)(2)(A) of the CSA, FDA, on behalf of the Department of Health and Human Services (HHS), invites interested persons to submit comments regarding the 26 named drugs. Any comments received will be considered by HHS when it prepares a scientific and medical evaluation of these drugs. HHS will forward a scientific and medical

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