801, 803, and 807, 809, and 820 (21 CFR parts 201, 207, 211, 600, 601, 606, 607, 610, 660, 801, 803, 807, 809, and 820). The collections of information in §§ 606.121, 606.122, and 610.40 have been approved under OMB Control No. 0910–0116; § 610.2 has been approved under OMB Control No. 0910–0206; §§ 600.12(e) and 600.80 have been approved under OMB Control No. 0910–0308; §§ 601.2(a), 601.12, 610.60 through 610.65, 610.67, 660.2(c), 660.28(a) and (b), 660.35(a), 660.35(c) through (g), 660.35(i) through (m), 660.45, and 660.55(a) and (b) have been approved under OMB Control No. 0910–0338; §§ 803.20, 803.50, and 803.53 have been approved under OMB Control No. 0910–0437; and §§ 600.14 and 606.171 have been approved under OMB Control No. 0910–0458. The current good manufacturing practice regulations for finished pharmaceuticals (part 211) have been approved under OMB Control No. 0910–0139; §§ 820.181 and 820.184 have been approved under OMB Control No. 0910–0073; the establishment registration regulations (parts 207, 607, and 807) have been approved under OMB Control Nos. 0910–0045, 0910–0052, and 0910–0387; and the labeling regulations (parts 201, 801, and 809) have been approved under OMB Control Nos. 0910–0537, 0910–0572, and 0910–0485.

Dated: February 25, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–6055 Filed 3–15–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0109]

Exchange of Letters Between Dr. Murray M. Lumpkin, Deputy Commissioner, International Programs, Food and Drug Administration and Mr. Martin Heraghty, Assistant Secretary General, Department of Agriculture, Fisheries and Food of Ireland Concerning Certification Requirements for Caseins, Caseinates, and Mixtures Thereof Exported From Ireland to the United States

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of exchange of letters between Dr. Murray M. Lumpkin, Deputy Commissioner, International and Special Programs, FDA and Mr. Martin Heraghty, Assistant Secretary General, Department of Agriculture, Fisheries and Food (DAFF), concerning certification requirements for caseins, caseinates, and mixtures thereof exported from Ireland to the United States.

The mutual goals of FDA and DAFF in establishing certification requirements for caseins, caseinates, and mixtures thereof exported from Ireland to the United States are to assure that contaminated products will not be imported into the United States and to minimize the need for extensive FDA audit sampling of these products from Ireland. DAFF and FDA have a history of cooperation on this issue and it is, therefore, desirable that the two Agencies continue to cooperate to maintain and improve consumer protection.

DATES: The agreement became effective November 10, 2010.

FOR FURTHER INFORMATION CONTACT: David P. Kelly, Office of International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 3404, Silver Spring, MD 20993–0002, 301–796–8373, *Fax:* 301–595–7941.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and understandings between FDA and others shall be published in the **Federal Register**, the Agency is publishing notice of this agreement.

Dated: March 10, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, Maryland 20903

NOV 10 2010

Martin Heraghty
Assistant Secretary General
Department of Agriculture, Fisheries and Food
Agriculture House
Kildare Street
Dublin 2
Ireland

Dear Mr. Heraghty:

It is with great pleasure that I express to you the intention of the United States Food and Drug Administration (FDA) to cooperate with the Department of Agriculture, Fisheries and Food (DAFF) of Ireland concerning certification requirements for caseins, caseinates, and mixtures thereof exported from Ireland to the United States.

The mutual goals of FDA and DAFF in establishing certification requirements for caseins, caseinates, and mixtures thereof exported from Ireland to the United States are to assure that contaminated products will not be imported into the U.S. and to minimize the need for extensive FDA audit sampling of these products from Ireland. FDA and DAFF have a history of cooperation on this issue and it is, therefore, desirable that the two agencies continue to cooperate to maintain and improve consumer protection.

FDA understands that DAFF intends to ensure that caseins, caseinates, and mixtures thereof that are intended for export to the United States are fit for human consumption in that they comply with the requirements of the Federal Food, Drug, and Cosmetic Act of the United States and the Public Health Service Act of the United States. DAFF will inspect and analyze samples of these caseins, caseinates, and mixtures thereof to ensure that they comply with these requirements.

To discharge its responsibilities regarding caseins, caseinates, and mixtures thereof, FDA understands that DAFF intends to:

1. Ensure each lot[1], as defined by the manufacturer has been analyzed to assure that it is Salmonella-negative[2] and phosphatase-negative[3].

2. Require that all of the information that is required by the Federal Food, Drug, and Cosmetic Act of the United States and the Fair Packaging and Labeling Act of the United States be included on the label and labeling of individual products.

3. Furnish FDA, upon request, with a full description of the manufacturing processes and quality controls used to ensure that the caseins, caseinates, and mixtures thereof that are produced are fit for human consumption.

FDA is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, certain provisions of the Public Health Service Act, and other related statutes of the United States. FDA directs its activities toward the protection of the public health in the United States by ensuring that foods are safe and wholesome and are honestly and informatively labeled. FDA accomplishes this goal in part through inspections of food processors and distributors. In addition, it collects and examines samples to ensure compliance with these statutes. FDA makes a concerted effort to ensure that foods entering the United States meet the same standards as domestic products.

To discharge these responsibilities regarding caseins, caseinates, and mixtures thereof, FDA intends to:

1. Audit samples of caseins, caseinates, and mixtures thereof certified by DAFF to ensure that the products exported from Ireland and offered for import into the United States comply with the requirements of the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, the Public Health Service Act, and other related statutes of the United States.

2. Share any information obtained through its audit sampling with DAFF and the first Secretary of the Embassy of Ireland in Washington.

3. Promptly notify DAFF and the First Secretary of the Embassy of Ireland in Washington of the detention of any caseins, caseinates, and mixtures thereof.

4. Share expertise and provide consultative assistance to DAFF when necessary to assure the safety of the caseins, caseinates, and mixtures thereof exported to the United States.

This letter is not intended to create obligations under international or other law, and all cooperation is subject to the availability of appropriated funds, personnel, and other resources. FDA and DAFF each intend to bear their own expenses associated with this cooperation. Either FDA or DAFF may terminate this cooperation on thirty (30) calendar days' written notice to the other. The cooperation will continue for a period of five (5) years from the last date of signature of this document and may be extended for additional five (5) year periods upon consent of FDA and DAFF. This cooperation supersedes the letters between FDA and DAFF regarding this same subject matter dated June 28 and 29, 2007.

I look forward to receipt of your affirmative reply.

Sincerely,

Murray M. Lumpkin, M.D., M.Sc.
Deputy Commissioner
International Programs
United States Food and Drug Administration

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, and website www.aoac.org.

Department of
Agriculture,
Fisheries and Food
An Roinn
Talmhaíochta,
Iascaigh agus Bia

4 November 2010

Murray M. Lumpkin, M.D., M.Sc.
Deputy Commissioner
International Programs
United States Food and Drug Administration

Dear Deputy Commissioner Lumpkin:

It is with great pleasure that I express to you the intention of the Department of Agriculture, Fisheries and Food (DAFF) of Ireland to cooperate with the United States Food and Drug Administration (FDA) concerning certification requirements for caseins, caseinates, and mixtures thereof exported from Ireland to the United States.

The mutual goals of DAFF and FDA in establishing certification requirements for caseins, caseinates, and mixtures thereof exported from Ireland to the United States are to assure that contaminated products will not be imported into the U.S. and to minimize the need for extensive FDA audit sampling of these products from Ireland. DAFF and FDA have a history of cooperation on this issue and it is, therefore, desirable that the two agencies continue to cooperate to maintain and improve consumer protection.

DAFF intends to ensure that caseins, caseinates, and mixtures thereof that are intended for export to the United States are fit for human consumption in that they comply with the requirements of the Federal Food, Drug, and Cosmetic Act of the United States and the Public Health Service Act of the United States. DAFF will inspect and analyze samples of these caseins, caseinates, and mixtures thereof to ensure that they comply with these requirements.

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1. Ensure each lot[1], as defined by the manufacturer has been analyzed to assure that it is Salmonella-negative[2] and phosphatase-negative[3].
2. Require that all of the information that is required by the Federal Food, Drug, and Cosmetic Act of the United States and the Fair Packaging and Labeling Act of the United States be included on the label and labeling of individual products.
3. Furnish FDA, upon request, with a full description of the manufacturing processes and quality controls used to ensure that the caseins, caseinates, and mixtures thereof that are produced are fit for human consumption.

FDA is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, certain provisions of the Public Health Service Act, and other related statutes of the United States. FDA directs its activities toward the protection of the public health in the United States by ensuring that foods are safe and wholesome and are honestly and informatively labeled. FDA accomplishes this goal in part through inspections of food processors and distributors. In addition, it collects and examines samples to ensure compliance with these statutes. FDA makes a concerted effort to ensure that foods entering the United States meet the same standards as domestic products.

Department of Agriculture, Fisheries and Food
An Roinn Talmhaíochta, Iascaigh agus Bia
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Telephone +353 (0)1 607 2000
Fax +353 (0)1 661 6263
info@agriculture.gov.ie
www.agriculture.gov.ie

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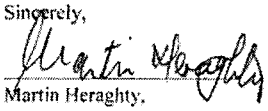
I look forward to receipt of your affirmative reply.

Sincerely,



Martin Heraghty,
Assistant Secretary General,
Department of Agriculture, Fisheries & Food
Ireland.

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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 and website www.aoac.org.

[FR Doc. 2011–6079 Filed 3–15–11; 8:45 am]
BILLING CODE 4160–01–C

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.*

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.

[FR Doc. 2011–6084 Filed 3–15–11; 8:45 am]
BILLING CODE 4160–01–P