riskassessmentsafetyassessment/ and at *http://www.regulations.gov.*

V. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses in this reference section, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Goulet, V., M. Hebert, C. Hedberg, et al., ''Incidence of Listeriosis and Related Mortality Among Groups at Risk of Acquiring Listeriosis.'' *Clinical Infectious Diseases,* 54(5): 652–660, 2012.
2. Scallan, E., R. M. Hoekstra, F. J. Angulo, et al., ''Foodborne Illness Acquired in the United States—Major Pathogens,'' *Emerging Infectious Diseases,* 17(1): 7–12, 2011.
3. U.S. Food and Drug Administration and Health Canada (2012). ''Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Draft Interpretative Summary.'' Accessible at *http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/default.htm.*
4. U.S. Food and Drug Administration and Health Canada (2012). ''Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Draft Technical Report.'' Accessible at *http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/default.htm.*
5. U.S. Food and Drug Administration and Health Canada (2012). ''Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Draft Technical Report Appendices.'' Accessible at *http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/default.htm.*
6. U.S. Food and Drug Administration and Health Canada (2012). ''Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Draft Risk Assessment Model.'' Analytica file. Accessible at *http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/default.htm.*
7. U.S. Food and Drug Administration and Health Canada (2012). ''Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Answer to the Peer Review.'' Accessible at *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm.*

Dated: February 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–02960 Filed 2–8–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0092]

Draft Guidance for Industry on Immunogenicity Assessment for Therapeutic Protein Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Immunogenicity Assessment for Therapeutic Protein Products.'' Therapeutic protein products may elicit immune responses, and these responses may lead to serious or life-threatening adverse events for the patient or loss of efficacy of the product. This draft guidance is intended to assist manufacturers to develop a risk-based approach in both the preclinical and clinical phases of the development of therapeutic protein products to evaluate and mitigate immune responses that may adversely affect their safety and efficacy.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 12, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amy Rosenberg, Center for Drug Evaluation and Research, Food and Drug Administration, 8800 Rockville Pike, Bldg. 29A, rm. 2D–16, Bethesda, MD 20892, 301–827–1790; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Immunogenicity Assessment for Therapeutic Protein Products.'' The purpose of this document is to assist manufacturers and clinical investigators involved in the development of therapeutic protein products for human use. The guidance outlines, and recommends adoption of, a risk-based approach to evaluating and mitigating the potential for immunogenicity that may affect the safety and efficacy of therapeutic protein products. The guidance describes various product- and patient-specific factors that can affect the immunogenicity of protein therapeutics and provides recommendations pertaining to each of these factors that may reduce the likelihood that these products will generate an immune response. In addition, the guidance offers a series of recommendations for risk mitigation in the clinical phase of development of protein therapeutics. The draft guidance also provides supplemental information on the diagnosis and management of particular adverse consequences of immune responses to protein therapeutics and contains brief discussions of the uses of animal studies and the conduct of comparative immunogenicity studies.

This 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 Agency's current thinking on immunogenicity assessment of therapeutic protein products. 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. 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.*

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: February 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Food and Drug Administration/Xavier University PharmaLink Conference—Quality in a Global Supply Chain

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District, in cosponsorship with Xavier University, is announcing a public conference entitled ''FDA/Xavier University PharmaLink Conference.'' The PharmaLink conference seeks solutions to important and complicated issues by aligning with the strategic priorities of FDA, and includes presentations from key FDA officials, global regulators, and industry experts. Each presentation challenges the status quo and conventional wisdom of our industry to create synergies focused on finding solutions which make a difference. Every discussion, exploration, and solution is framed by the goal of delivering increased patient health and safety through topics such as a working session with the Office of the Commissioner on the implementation of the FDA Safety and Innovation Act, Business Impact of Outsourcing, Supplier Management Models that Work, Implementing Quality by Design (QbD) Successfully—like other industries, lunch with global regulators (FDA, Medicines and Healthcare products Regulatory Agency (MHRA), Fimea, and Swissmedic), and many more. The experience level of our audience has fostered engaged dialog that has led to innovative initiatives.

DATES: The public conference will be held on March 12, 2013, from 8:30 a.m. to 5 p.m.; March 13, 2013, from 8:30 a.m. to 5 p.m.; and March 14, 2013, from 8:30 a.m. to 12:45 p.m.

ADDRESSES: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513–745–3073 or 513–745–3396.

FOR FURTHER INFORMATION CONTACT:

For information regarding this notice: Steven Eastham, Office of Regulatory Affairs, Food and Drug Administration, Cincinnati South Office, 36 East 7th Street, suite 1910, Cincinnati, OH 45202, 513–246–4134, email: *steven.eastham@fda.hhs.gov.*

For information regarding the conference and registration: Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513–745–3073, email: *phillipsm4@xavier.edu.*

SUPPLEMENTARY INFORMATION:

Registration: There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, lunches, and dinners for the 2½ days of the conference. Advanced registration rate ends February 18, 2013. Standard registration rates begin on February 19, 2013. There will also be onsite registration. The cost of registration is as follows:

TABLE 1—REGISTRATION FEES [1]

Attendee type	Fee Jan. 23–Feb. 18	Fee after Feb. 18
Industry	$1,295	$1,495
Small Business (<100 employees)	900	1,000
Consultants	600	700
Startup Manufacturer	250	300
Academic	250	300
Media	Free	Free
Government	Free	Free

[1] The fourth registration from the same company is free—all four attendees must register at the same time.

The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks.

To register online for the public conference, please visit the ''Registration'' link on the conference Web site at *http://www.XavierPharmaLink.com.* FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register.**

To register by mail, please send your name, title, firm name, address, telephone and fax numbers, email, and payment information for the fee to Xavier University, Attention: Susan Bensman, 3800 Victory Pkwy., Cincinnati, OH 45207. An email will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarter hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 West 5th Street, Cincinnati, OH 45202, 513–421–9100. To make reservations online, please visit the ''Venue & Logistics'' link at *http://www.XavierPharmaLink.com.* The hotel is expected to sell out during this timeframe, so early reservation in the conference room block is encouraged.

If you need special accommodations due to a disability, please contact Marla Phillips (see **FOR FURTHER INFORMATION**