Authority: 44 U.S.C. 3101.

Dated: October 13, 2011.

Michelle Snyder,

Deputy Chief Operating Officer, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–27169 Filed 10–19–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0720]

International Conference on Harmonisation; E2B(R3) Electronic Transmission of Individual Case Safety Reports; Draft Guidance on Implementation; Data Elements and Message Specification; Appendix on Backwards and Forwards Compatibility; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''E2B(R3) Electronic Transmission of Individual Case Safety Reports (ICSRs): Implementation Guide—Data Elements and Message Specification'' (the draft E2B(R3) implementation guidance) and an appendix to the draft guidance entitled ''ICSRs: Appendix to the Implementation Guide—Backwards and Forwards Compatibility'' (the draft BFC appendix). The draft E2B(R3) implementation guidance and draft BFC appendix were prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft E2B(R3) implementation guidance is intended to revise the standards for submission of ICSRs and improve the inherent quality of the data, enabling improved handling and analysis of ICSR reports. The draft BFC appendix describes the relationship between data elements from the 2001 ICH E2B guidance and draft E2B(R3) implementation guidance.

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 these draft documents before it begins work on the final versions of the documents, submit either electronic or written comments on the draft documents by January 18, 2011.

ADDRESSES: Submit written requests for single copies of the draft documents to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft documents may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft documents.

Submit electronic comments on the draft documents 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:

Regarding the guidance:

Krishna K. Chary, Center for Drug Evaluation and Research, Food and Drug Administration, 8201 Corporate Dr., suite 540, Landover, MD 20785, 240–487–7377, *fax:* 301–459–2285, *e-mail: krishna.Chary@fda.hhs.gov;* or

Deborah F. Yaplee, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3288, *fax:* 301–827–9434, *e-mail: deborah.yaplee@fda.hhs.gov.*

Regarding the ICH:

Michelle Limoli, Office of International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 3506, Silver Spring, MD 20993, 301–796–4600.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory Agencies.

The ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In June and July 2011, the ICH Steering Committee agreed that a draft guidance entitled ''E2B(R3) Electronic Transmission of Individual Case Safety Reports (ICSRs): Implementation Guide—Data Elements and Message Specification'' and a draft appendix entitled ''ICSRs: Appendix to the Implementation Guide—Backwards and Forwards Compatibility'' should be made available for public comment. The documents are the product of the E2B(R3) Expert Working Group of the ICH. Comments about these documents will be considered by FDA and the E2B(R3) Expert Working Group.

The key intention of the draft E2B(R3) implementation guidance is to revise the standards for submission of ICSRs and improve the inherent quality of the data, enabling improved handling and analysis of ICSRs. The draft E2B(R3) implementation guidance provides support for the implementation of software tools for creating, editing, sending, and receiving electronic ICSR messages. The draft E2B(R3) implementation guidance provides instruction for how pharmaceutical industries and regulatory authorities should use Part 2 of the International Organization for Standardization (ISO) ICSR standard to construct messages for exchanging pharmacovigilance information among themselves in ICH regions, and in other countries adopting ICH guidelines. The draft BFC appendix describes the relationship between data

elements from E2B(R2) and E2B(R3) and is intended to assist reporters and recipients in implementing systems with special focus on the recommendations for converting back and forth between E2B(R2) and E2B(R3) ICSR reports. The draft E2B(R3) implementation guidance and draft BFC appendix are being issued as a package that includes schema files and additional technical information.

The draft E2B(R3) implementation guidance and BFC appendix are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The documents, when finalized, will represent the Agency's current thinking on this topic. The documents do not create or confer any rights for or on any person and do 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 to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding these documents. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

III. Electronic Access

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

Dated: October 17, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–27147 Filed 10–19–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee: Notice of Postponement of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is postponing the meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee scheduled for December 1, 2011. The meeting was announced in the **Federal Register** of Friday, October 7, 2011 (76 FR 62419). The meeting is postponed so that FDA can review and consider additional information that was submitted. A future meeting date will be announced in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Avena Russell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring, MD 20993–0002, 301–796–3805, e-mail: *Avena.Russell@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

Dated: October 14, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–27209 Filed 10–19–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0731]

Risk Assessment on Norovirus in Bivalve Molluscan Shellfish: Request for Comments and for Scientific Data and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and for scientific data and information.

SUMMARY: The Food and Drug Administration (FDA) is undertaking a collaboration with Health Canada, the Canadian Food Inspection Agency, Environment Canada, and Fisheries and Oceans Canada, to conduct a quantitative food safety risk assessment on norovirus in bivalve molluscan shellfish, specifically, oysters, clams, and mussels. FDA, on behalf of the collaborative team, is requesting submission of comments and scientific data and information that would assist in the development of the risk assessment.

DATES: Submit either electronic or written comments and scientific data and information by January 18, 2012.

ADDRESSES: Submit electronic comments and scientific data and information to *http://www.regulations.gov.* Submit written comments and scientific data and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jane M. Van Doren, Center for Food Safety and Applied Nutrition (HFS—005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2927.

SUPPLEMENTARY INFORMATION:

I. Background

Noroviruses constitute a genus of genetically diverse, single-stranded ribonucleic acid (RNA) viruses belonging to the family Caliciviridae (Ref. 1). Noroviruses cause millions of cases of acute gastroenteritis in the United States and thousands of cases in Canada annually (Refs. 2 to 4). The viruses can be transmitted through consumption of norovirus-contaminated food or water, through person-to-person contact, or through contact with contaminated surfaces (Refs. 1 and 5). Most norovirus outbreaks attributed to bivalve molluscan shellfish consumption have been traced to contamination during growth and harvest (Refs. 1 and 6). Bivalve molluscan shellfish are typically grown in estuaries, which may contain norovirus-contaminated human fecal material from municipal wastewater outfalls, combined sewer overflow, or non-point sources of pollution including human waste discharged from marine vessels (Refs. 6 to 8). Under some conditions, bivalve molluscan shellfish bioaccumulate waste contaminants (Ref. 9), thereby increasing the contaminant level in the bivalve molluscan shellfish relative to that in the water.

Both the United States and Canada have developed detailed guidelines, in collaboration with their respective federal, state or provincial, tribal, and industry partners, to help ensure