

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]

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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 Calciviridae (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