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]

BILLING CODE 4160–01–P

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

shellfish food safety. The requirements described in these documents (Refs. 10 and 11) reflect a risk-based approach to reduce levels of indicator organisms, including total and fecal coliforms, thereby decreasing the probability of pathogenic contamination of shellfish.

FDA, in collaboration with Health Canada, the Canadian Food Inspection Agency, Environment Canada, and Fisheries and Oceans Canada (the joint U.S.-Canada risk assessment team), is planning to conduct a quantitative risk assessment that can be used to evaluate the impact of preventive practices and controls on the risk of human norovirus illness associated with consumption of bivalve molluscan shellfish. The risk assessment will focus on norovirus contamination of bivalve molluscan shellfish arising from growth, harvest, and post-harvest processing. This risk assessment will focus on oysters, clams, and mussels. The principal objectives of this risk assessment are to:

- Evaluate the relative impact of selected factors (e.g., size of the community contributing to the municipal wastewater catchment, wastewater treatment, water temperature in bivalve molluscan shellfish growing and harvest areas, harvest season, post-harvest processes, food production practices, and consumption patterns) on the risk of human norovirus illness associated with the consumption of bivalve molluscan shellfish;
- Assess the impact on the level of risk of specified control measures currently used to mitigate risks from norovirus contamination of bivalve molluscan shellfish growing waters including those recommended by National Shellfish Sanitation Program (NSSP) and Canadian Shellfish Sanitation Program (CSSP);
- Identify additional preventive practices and controls that could be implemented in the future; and
- Inform the development of a Food Safety Objective (Ref. 12) for norovirus contamination in bivalve molluscan shellfish and/or a Performance Objective (Ref. 12) for bivalve molluscan shellfish growth and harvest waters.

Contamination arising from transmission of norovirus from infected or ill food workers in food manufacturing or retail establishments to bivalve molluscan shellfish is outside the scope of this risk assessment.

II. Request for Comments, Scientific Data, and Information

FDA, on behalf of the joint U.S.-Canada risk assessment team, is requesting comments, scientific data, and information to be considered in the design and development of the risk assessment. Data that include measurements of norovirus or enteric viral surrogate should identify the methods of analysis and detection, virus/surrogate and genotype detected, and recovery rate, if available (e.g., analysis of single oyster diverticulum using real-time reverse transcription quantitative polymerase chain reaction (RT-qPCR) for norovirus GII with 80% recovery). Areas of particular interest include epidemiology of norovirus illness, pre-harvest preventive practice and controls, post-harvest preventive practices and controls, food preparation and consumption practices, and the relationship between norovirus dose and adverse health effects.

A. Epidemiology of Norovirus Illness

We request data and information about the following aspects of the epidemiology of norovirus illness:

1. Patterns of transmission of norovirus in different settings, such as in a community, a nursing facility, or a household;
2. Proportion of norovirus illness due to person-to-person transmission, food consumption, and bivalve molluscan shellfish consumption;
3. Proportion and determinants of individual resistance to norovirus infection;
4. Underreporting rate for norovirus illnesses arising from consumption of norovirus-contaminated food in United States or Canada; and
5. Models describing the transmission of norovirus in a population.

B. Preventive Practices and Controls and Other Factors Influencing Bivalve Molluscan Shellfish Contamination Levels

We request data and information about the following aspects of preventive practices and controls and other factors influencing bivalve molluscan shellfish contamination levels:

1. Prevalence of different types of treatment in municipal wastewater treatment (WWT) facilities in the United States and Canada, their relative size (population served), and their location relative to bivalve molluscan shellfish growing/harvest areas. Data submitted should also include information about treatment process(es) (e.g., sequence,timing, and/or concentration of bacteria/viral reducing agent) and effluent flow (volumerates of flow observed in the facility and the factors that influence the rate);
2. Norovirus or enteric viral surrogate loads in raw wastewater and treated effluent from municipal WWT facilities as a function of type of treatment, water temperature, and season. Data should include the date and time of the measurement, volume rate of flow, weather, size of the community served, and the presence of norovirus outbreaks in the population at the time of measurement (if known). FDA specifically requests comparisons of norovirus or enteric viral surrogate loads in raw wastewater and WWT effluent obtained during the same time period and from the same facility;
3. Experimental data and models describing dilution of WWT effluent in the estuary (e.g., water exchange rate and tidal flush volume) for a representative estuary or estuaries in general. Information should include details on calculations used within the model;
4. Experimental data and models describing norovirus or enteric viral surrogate loss processes that may occur in an estuary, including inactivation by ultraviolet radiation or sunlight, association with particulate followed by sedimentation, and predation by marine organisms. Data submitted should include experimental conditions and ranges (e.g., water temperature, water salinity, season, and estuary water exchange rate);
5. Concentration of norovirus or enteric viral surrogates in sediments, events that cause re-suspension of sediment, and data describing the relationship between nearby sediment and the concentration of norovirus or enteric viral surrogates in bivalve molluscan shellfish. Data submitted should include information about the sediment sampled (e.g., depth, temperature, water salinity, season) and shellfish sampled (e.g., nutrient availability, growth substrate, water temperature, water salinity, season, species, and animal variance), if applicable;
6. Characteristics of sites where stratification of WWT effluent discharge in the water column occurs (e.g., temperature, salinity, depth, surface winds, storm activity, local hydrodynamics, and outfall design) and the impact of these characteristics on norovirus or enteric viral surrogate concentrations in bivalve molluscan shellfish growing/harvest areas (e.g., plume movement and mixing);
7. Norovirus or enteric viral surrogate loads from marine vessel discharge, combined sewer overflow, or other sporadic events that might contaminate bivalve molluscan shellfish growing/harvest areas;
8. Uptake rate of norovirus or enteric viral surrogates by bivalve molluscan shellfish and determinations of the

bioaccumulation factor (BAF). Data and information should include a description of the impacts of pathogen particle association, concentration of the pathogen in the water surrounding the bivalve molluscan shellfish, nutrient availability, growth substrate, water temperature, water salinity, season, species, and animal variance on this rate and the BAF. Data submitted should specify the experimental conditions during which uptake was measured (e.g., batch feeding, flow-through feeding, or natural environmental conditions);

9. Inactivation rate of norovirus or enteric viral surrogates within bivalve molluscan shellfish, including the impacts of nutrient availability, growth substrate, water temperature, water salinity, season, species, and animal variance on this rate. Data submitted should specify the experimental conditions during which inactivation was measured (e.g., batch, flow-through, or natural environmental conditions);

10. Elimination rate of norovirus or enteric viral surrogates from bivalve molluscan shellfish including the impacts of nutrient availability, growth substrate, water temperature, water salinity, season, species, and animal variance on this rate. Data submitted should specify the experimental conditions during which elimination was measured (e.g., batch, flow-through, or natural environmental conditions); and

11. Models that specifically address uptake, inactivation and elimination of norovirus or enteric viral surrogates by bivalve molluscan shellfish.

C. Post-Harvest Preventive Practice and Controls and Other Factors Influencing Bivalve Molluscan Shellfish Contamination Levels

We request data and information about the following aspects of post-harvest preventive practice and controls and other factors influencing bivalve molluscan shellfish contamination levels:

1. Regional and seasonal landings of bivalve molluscan shellfish species in the United States and Canada;

2. Prevalence and concentration of norovirus or enteric viral surrogates in bivalve molluscan shellfish at the time of harvest, classified by species, location, and seasonal landing;

3. Proportion of bivalve molluscan shellfish, by species, that undergo wet storage, relaying and depuration and the conditions (e.g., times and temperatures) of these practices as applied by the shellfish industry. Data are also requested to determine whether shellfish undergoing these different treatments preferentially serve different postmarkets (e.g., raw/cooked);

4. Experimental data and models that describe the impact of wet storage, relaying, and depuration on the concentration of norovirus or enteric viral surrogate in bivalve molluscan shellfish. Data submitted should specify process and experimental conditions including parameter ranges (e.g., process time, water temperature, water salinity, nutrient availability, growth substrate, species, and season) as well as animal variance;

5. Proportion of bivalve molluscan shellfish, by species, that undergo high hydrostatic pressure (HHP), mild heat, irradiation, freezing, or other postharvest processes. Data are also requested to determine whether bivalve molluscan shellfish undergoing these different treatments preferentially serve different postmarkets (e.g., raw/cooked);

6. Protocols/conditions and parameter ranges for HHP, mild heat, irradiation, freezing, or other postharvest processes as applied to bivalve molluscan shellfish by the shellfish industry; and

7. Experimental data and models that describe the impact of HHP, mild heat, irradiation, freezing, or other post-harvest processes on the concentration of norovirus or enteric viral surrogate in bivalve molluscan shellfish. Data submitted should specify the processing and experimental conditions, parameter ranges (e.g., time, pressure and temperature), species, and animal variance.

D. Preventive Practice and Controls and Other Factors Influencing Bivalve Molluscan Shellfish Contamination Levels During Food Preparation and Bivalve Molluscan Shellfish Consumption Data

We request data and information about the following aspects of preventive practice and controls and other factors influencing bivalve molluscan shellfish contamination levels during food preparation and bivalve molluscan shellfish consumption:

1. Proportion of bivalve molluscan shellfish, by species, eaten raw and cooked, including method of cooking (e.g., steaming, frying, or baking);

2. Distribution of bivalve molluscan shellfish meal sizes, categorized by species, with regard to season, region, and preparation technique;

3. Distribution of temperatures and times associated with cooking methods (e.g., steaming, frying, or baking) for bivalve molluscan shellfish, by species;

4. Experimental data and models describing the impact of food preparation technique on the concentration of norovirus or enteric viral surrogates in bivalve molluscan shellfish, by species. Data submitted should include food preparation and cooking parameters and ranges (e.g., temperature and time); and

5. Prevalence distribution of norovirus or enteric viral surrogate in bivalve molluscan shellfish, by species, at the point of consumption as a function of season, region and preparation technique.

E. Relationship Between Norovirus Dose and Adverse Human Health Effects

We request data and information about the following aspects of the relationship between norovirus dose and adverse human health effects including:

1. Human or animal studies that describe the relationship between norovirus dose and the probability and severity of human illness;

2. Human norovirus outbreak data that describe the relationship between norovirus dose and the probability and severity of human illness; and

3. Epidemiological and mechanistic data identifying/describing different rates of illness or health outcomes for particular populations (e.g., vulnerable/susceptible populations and resistant populations) exposed to norovirus.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and scientific data and information regarding this document. It is only necessary to send one set of comments and scientific data and information. It is no longer necessary to send two copies of mailed comments and scientific data and information. Identify comments and scientific data and information with the docket number found in brackets in the heading of this document. Received comments and scientific data and information may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. 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. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Centers for Disease Control and Prevention, Norovirus Technical Fact

Sheet, *http://www.cdc.gov/ncidod/dvrd/revb/gastro/norovirus-factsheet.htm.*

2. Centers for Disease Control and Prevention, Norovirus: Surveillance, Disease Burden, and Disease Reduction Activities, *http://www.cdc.gov/ncidod/dvrd/revb/gastro/norovirus-surv-disease-burden.htm.*

3. National Microbiology Laboratory and Public Health Agency of Canada, National Enteric Surveillance Program, ''Annual Summary of Laboratory Surveillance Data for Enteric Pathogens in Canada,'' 2009.

4. Majowicz, S.E., V.L. Edge, A. Fazil, *et al.,* ''Estimating the Under-Reporting Rate for Infectious Gastrointestinal Illness in Ontario,'' *Canadian Journal of Public Health,* vol. 96, pp. 178–181, 2005.

5. Gerba, C.P. and D. Kayed, ''Caliciviruses: A Major Cause of Foodborne Illness,'' *Journal of Food Science,* vol. 68, pp. 1136–1142, 2003.

6. Kohn, M.A., T.A. Farley, T. Ando, *et al.,* ''An Outbreak of Norwalk Virus Gastroenteritis Associated With Eating Oysters: Implications for Maintaining Safe Oyster Beds,'' *Journal of the American Medical Association,* vol. 273, pp. 466–471, 1995.

7. Shieh, Y.C., R.S. Baric, J.W. Woods, *et al.,* ''Molecular Surveillance of Enterovirus and Norwalk-Like Virus in Oysters Relocated to a Municipal-Sewage-Impacted Gulf Estuary,'' *Applied and Environmental Microbiology,* vol. 69, pp. 7130–7136, 2003.

8. J.A. Lowther, K. Henshilwood, and D.N. Lees, ''Determination of Norovirus Contamination in Oysters From Two Commercial Harvesting Areas Over an Extended Period, Using Semiquantitative Real-Time Reverse Transcription PCR,'' *Journal of Food Protection,* vol. 71, pp. 1427–1433, 2008.

9. Burkhardt, W., III and K. Calci, ''Selective Accumulation May Account for Shellfish-Associated Viral Illness,'' *Applied Environmental Microbiology,* vol. 66, pp. 1375–1378, 2000.

10. National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish 2009 Revision, *http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationProgram/ucm046353.htm.*

11. Canadian Shellfish Sanitation Program (CSSP) Manual of Operations, *http://www.inspection.gc.ca/english/fssa/fispoi/man/cssppccsm/shemolalle.pdf.*

12. Joint Food and Agriculture Organization of the United Nations/World Health Organization Food Standards Program, Codex Alimentarius Commission Procedural Manual, 20th ed. 113, 2011, *ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_20e.pdf.*

Dated: October 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–27101 Filed 10–19–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging

ACTION: Notice of Closed Meeting.

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Mechanisms of Osteoporosis II.

Date: November 15, 2011.

Time: 12 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Alexander Parsadanian, PhD, Scientific Review Officer, National Institute on Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *Parsadaniana@NIA.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: October 14, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–27180 Filed 10–19–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Collaborative: PAR 09–153 R01s for Clinical and Services Studies of Mental Disorders, AIDS and Alcohol Use Disorders.

Date: November 9, 2011.

Time: 9 a.m. to 10 a.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Wardman Park Washington, DC Hotel, 2660 Woodley Road, NW., Washington, DC 20008.

Contact Person: Mark P Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1775, *rubertm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: HIV/AIDS Innovative Research Applications.

Date: November 9, 2011.

Time: 10 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Wardman Park Washington, DC Hotel. 2660 Woodley Road, NW., Washington, DC 20008.

Contact Person: Mark P. Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1775, *rubertm@csr.nih.gov.*

Name of Committee: AIDS and Related Research Integrated Review Group, AIDS Molecular and Cellular Biology Study Section.

Date: November 21, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications. Ritz Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

Contact Person: Kenneth A. Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214,