11. Litigation, Opposing Counsel: A record from this system of records may be disclosed to a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations or in connection with criminal law proceedings or in response to a subpoena.

12. NARA/Records Management: A record from this system of records may be disclosed to the National Archives and Records Administration (NARA) or other Federal Government agencies pursuant to the Federal Records Act.

13. Security Threat: A record from this system of records may be disclosed to Federal and foreign government intelligence or counterterrorism agencies when FRTIB reasonably believes there to be a threat or potential threat to national or international security for which the information may be useful in countering the threat or potential threat, when FRTIB reasonably believes such use is to assist in anti-terrorism efforts, and disclosure is appropriate to the proper performance of the official duties of the person making the disclosure.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in paper and electronic form, including on computer databases and cloud-based services, all of which are securely stored.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by employee/contractor name or user ID.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records are maintained in accordance with General Records Schedule 3.2 (Information Systems Security Records), Items 030 and 031, issued by the National Archives and Records Administration (NARA).

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

FRTIB has adopted appropriate administrative, technical, and physical controls in accordance with FRTIB's security program to protect the security, confidentiality, availability, and integrity of the information and to ensure that records are not disclosed to or accessed by unauthorized individuals.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records within this system must submit a request pursuant to 5 CFR part 1630. Attorneys or other persons acting on behalf of an individual must provide written authorization from that individual, such as a Power of Attorney, in order for the representative to act on their behalf.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

See Record Access Procedures above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

[FR Doc. 2019–18034 Filed 8–20–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Fees for Sanitation Inspection of Cruise Ships

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: General notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) announces fees for vessel sanitation inspections for Fiscal Year (FY) 2020. These inspections are conducted by HHS/CDC's Vessel Sanitation Program (VSP). VSP helps the cruise line industry fulfill its responsibility for developing and implementing comprehensive sanitation programs to minimize the risk for acute gastroenteritis. Every vessel that has a foreign itinerary and carries 13 or more passengers is subject to twice-yearly unannounced operations inspections and, when necessary, re-inspection.

DATES: These fees apply to inspections conducted from October 1, 2019, through September 30, 2020.

FOR FURTHER INFORMATION CONTACT: CDR Aimee Treffiletti, Chief, Vessel Sanitation Program, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS F–59, Atlanta, Georgia 30341–3717; phone: 800–323–2132; email: *vsp@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose and Background

HHS/CDC established the Vessel Sanitation Program (VSP) in the 1970s as a cooperative activity with the cruise ship industry. VSP helps the cruise ship industry prevent and control the introduction, transmission, and spread of gastrointestinal illnesses on cruise ships. VSP operates under the authority of the Public Health Service Act (Section 361 of the Public Health Service Act; 42 U.S.C. Section 264, ''Control of Communicable Diseases''). Regulations found at 42 CFR 71.41 (Foreign Quarantine—Requirements Upon Arrival at U.S. Ports: Sanitary Inspection; General Provisions) state that carriers arriving at U.S. ports from foreign areas are subject to sanitary inspections to determine whether there exists rodent, insect, or other vermin infestations; contaminated food or water; or other sanitary conditions requiring measures for the prevention of the introduction, transmission, or spread of communicable diseases.

The fee schedule for sanitation inspections of passenger cruise ships by VSP was first published in the **Federal Register** on November 24, 1987 (52 FR 45019). HHS/CDC began collecting fees on March 1, 1988. This notice announces fees for inspections conducted during FY 2020 (beginning on October 1, 2019, through September 30, 2020).

The following formula will be used to determine the fees:

$$\textit{Average cost per inspection} = \frac{\textit{Total cost of VSP}}{\textit{Weighted number of annual inspections}}$$

Total cost of VSP = Total cost of operating the program, such as administration, travel, staffing, sanitation inspections, and outbreak response. Weighted number of annual inspections = Total number of ships and inspections per year accounting for vessel size, number of inspectors needed for vessel size, travel logistics to conduct inspections, and vessel location and arrivals in U.S. jurisdiction per year.

The fee schedule was most recently published in the **Federal Register** on June 20, 2018 (83 FR 28650). The fee

schedule for FY 2020 is presented in Appendix A.

Fee

The fee schedule (Appendix A) applies to inspections conducted from October 1, 2019, through September 30, 2020. The FY 2020 fee schedule adds a new category and fee for the largest ships (Super Mega) and a schedule table for construction and renovation inspections.

Applicability

The fees will apply to all passenger cruise vessels for which inspections are conducted as part of HHS/CDC's VSP.

Dated: August 14, 2019.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

Appendix A

FEE SCHEDULE FOR EACH VESSEL SIZE—OPERATIONS INSPECTIONS

Vessel size (GRT [1])	Inspection fee (US$)
Extra Small (<3,000 GRT)	1,495
Small (3,001–15,000 GRT) ..	2,990
Medium (15,001–30,000 GRT)	5,980
Large (30,001–60,000 GRT)	8,970
Extra Large (60,001–120,000 GRT)	11,960
Mega (120,001–140,000 GRT)	17,940
Super Mega (>140,001 GRT) *	23,920

* *New vessel size category.*

[1] Gross register tonnage in cubic feet, as shown in Lloyd's Register of Shipping.

Operations inspections and re-inspections involve the same procedures and require the same amount of time, so they are charged at the same rates.

FEE SCHEDULE FOR EACH VESSEL SIZE—CONSTRUCTION/RENOVATION INSPECTIONS

Vessel size (GRT [1])	Inspection fee (US$)
Extra Small (<3,000 GRT)	2,990
Small (3,001–15,000 GRT) ..	5,980
Medium (15,001–30,000 GRT)	11,960
Large (30,001–60,000 GRT)	17,940
Extra Large (60,001–120,000 GRT)	23,920
Mega (120,001–140,000 GRT)	35,880
Super Mega (>140,001 GRT) *	47,840

* *New vessel size category.*

[1] Gross register tonnage in cubic feet, as shown in Lloyd's Register of Shipping.

Construction/renovations inspections require at least twice the amount of time as operations inspections, so they are charged double the rates.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3617]

Joint Pediatric Advisory Committee and Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pediatric Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The general function of the committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on September 26, 2019, from 9 a.m. to 4:40 p.m.

ADDRESSES: The meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Building 31, Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2019–N–3617. The docket will close on September 24, 2019. Submit either electronic or written comments on this public meeting by September 24, 2019. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 24, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before September 12, 2019, will be provided to the committees. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate. You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–3617 for ''Joint Pediatric Advisory Committee and Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received