respondent burden. The total annual burden hours are 500.

Project	No. of respondents	No. of responses/ respondent	Avg. burden/ response (in hrs.)
QDRL Laboratory Interviews:			
(1) NHIS modules	150	1	1.0
(2) Behavioral Risk Factors Survey	100	1	1.0
(3) Other Questionnaire Testing:			
1998	200	1	1.0
1999	200	1	1.0
2000	200	1	1.0
(4) Perceptions of Quality of Life Project	100	1	1.0
(5) Perceptions of Confidentiality Project	50	1	1.0
(6) Perception of Statistical Maps Project	100	1	1.0
(7) General Methodological Research	200	1	0.5
Pilot Household Interviews:			
1999 NHIS Modules	100	1	1.0
2000 NHIS Modules	100	1	1.0
2001 NHIS Modules	100	1	1.0

Dated: November 10, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning And Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–30099 Filed 11–14–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee for Injury Prevention and Control Meeting: Change of Time and Location

Federal Register Citation of Previous Announcement: 62 FR 54639—dated October 21, 1997.

SUMMARY: Notice is given that the meeting time and location of the Advisory Committee for Injury Prevention and Control (ACIPC) has changed. The meeting date, status, purpose, and matters to be discussed announced in the original notice remain unchanged. There will be no change in the meeting location of the Science and Program Review Work Group, which will be meeting prior to the full Committee from 1–1:45 p.m. at the Sheraton Washington Hotel.

Original Time and Location: 1–4:30 p.m., Sheraton Washington Hotel, 2660 Woodley Road at Connecticut Avenue, NW, Washington, DC 20008.

New Time and Location: 2–4:30 p.m., Omni Shoreham Hotel, 2500 Calvert Street, NW, Washington, DC 20008.

CONTACT PERSON FOR MORE INFORMATION: Thomas E. Blakeney, Executive Secretary, ACIPC, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway, NE, M/S K61, Atlanta, Georgia 30341–3724, telephone 770/488–1481.

Dated: November 10, 1997.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–30098 Filed 11–14–97; 8:45 am]

BILLING CODE 4163–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Fees for Sanitation Inspections of Cruise Ships and Consultation Services for Ship Construction and Renovation

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

ACTION: Notice and request for public comment.

SUMMARY: This notice announces fees for vessel sanitation inspections effective January 1, 1998. The Public Health Service (PHS) proposes an additional vessel size category for ships >90,000 gross register tonnage. The purpose of the new ''Mega'' size category is to more accurately recover costs of the Vessel Sanitation Program (VSP) for conducting sanitary inspections of these super-large ships. The PHS also proposes to begin charging fees for consultation services for ship construction and renovation. The purpose of these charges would be to recover costs of conducting the consultation services for ship construction and renovation.

Public comment is requested on the proposed administrative policies to add the new size category for inspections, and to charge for consultation services for ship construction and renovation.

DATES: To ensure consideration, respondents must have their written comments regarding the new size category and charges for services for ship construction and renovation to the VSP by January 2, 1998. Fees for vessel sanitation inspections are effective January 1, 1998.

ADDRESSES: Written comments should be sent by mail or facsimile to the Vessel Sanitation Program, Special Programs Group, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., (F16), Atlanta, Georgia 30341–3724, facsimile (770) 488–4127.

FOR FURTHER INFORMATION CONTACT: Daniel M. Harper, Program Manager, Vessel Sanitation Program, National Center for Environmental Health, telephone (770) 488–7093 or e-mail DMH2@CDC.GOV, or Dave Forney, Public Health Advisor, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, telephone (770) 488–7333 or e-mail DLF1@CDC.GOV.

SUPPLEMENTARY INFORMATION:

Purpose and Background

The Centers for Disease Control and Prevention (CDC) operates a vessel sanitation inspection program for cruise ships with international itineraries and calling at United States ports under sections 361–369 (42 U.S.C. 264–272) of the Public Health Service Act, as amended. Regulations for the inspection program appear at 42 CFR part 71.

The Vessel Sanitation Program is a cooperative activity between the cruise ship industry and CDC. The purpose and goals of the VSP are to achieve and maintain a level of sanitation that will lower the risk for gastrointestinal disease outbreaks and assist the passenger line industry in its effort to provide a healthful environment for passengers and crew.

The fee schedule for sanitation inspections of passenger cruise ships currently inspected under the VSP was first published in the **Federal Register** on November 24, 1987 (52 FR 45019), and revised in a schedule published in the **Federal Register** on November 28, 1989 (54 FR 48942). Since then, CDC has published the fee schedule annually. The purpose of this notice is to announce the revised fee schedule for the period January 1, 1998, through September 31, 1998. Public comment is also being requested on the proposal to create a new ''Mega'' category and on the proposal to charge fees for consultation services for ship construction and renovation.

Revised Inspection Fee Schedule

This notice announces fees effective January 1, 1998. The proposed revised size/cost factor is presented in Appendix A. The formula used to determine the fees is as follows:

$$\text{Average cost per inspection} = \frac{\text{Total Cost of VSP}}{\text{Weighted No. of Annual Inspections}}$$

The average cost per inspection is multiplied by a size/cost factor to determine the fee for vessels in each size category. The fee schedule for sanitation inspections is presented in Appendix A and will be effective January 1, 1998, through September 30, 1998. Beginning October 1, 1999, all VSP fiscal activities will be on a Federal fiscal year basis (October 1–September 30). Should a substantial increase occur in the cost of air transportation, it may be necessary to readjust the fees before September 30, 1998, since travel constitutes a sizable portion of the costs of this program. If such a readjustment in the fee schedule is necessary, a notice will be published in the **Federal Register** 30 days before the effective date.

Calender year 1997 opened with the delivery of the first cruise ship exceeding 100,000 gross tonnage. Records for new ship construction document that additional ships of equal or greater tonnage are coming into the U.S. market in 1998 and beyond. As set out in Appendix A, the PHS proposes an additional vessel size category for ships >90,000 gross register tonnage. The purpose of the new ''Mega'' size category is to more accurately recover the VSP's costs for conducting sanitary inspections of these super-large ships.

Construction and Renovation Consultation Fees

As part of the program designed to assist cruise ship operators in achieving and maintaining a healthy level of sanitation, the VSP offers consultative services upon the request of a ship's owner or operator. The VSP staff review ship construction or renovation plans before construction begins and conduct on-site inspections of the cruise ship during construction as needed. After each review or inspection, VSP staff members issue a written advisory report summarizing any recommended changes to conform to CDC inspection guidelines.

The proposed fees for consultation services by VSP for ship construction and renovation will be three times the cost of a routine sanitation inspection of a passenger cruise ship (based on tonnage) inspected under the VSP, plus travel and per diem costs. The fee schedule for sanitation inspections of passenger cruise ships is published annually in the **Federal Register** and is determined by dividing the full cost of the VSP by the estimated number of inspections and multiplying by a size/cost factor based on the size of the vessel and the number of vessels in each category.

The proposed fee structure for consultation services is based on the following time commitment from two VSP inspectors:

Gross tonnage	Number of days for plan reviews	Number of days for office consultations	Number of days for shipyard visit (including travel)	Initial U.S. inspection	Total number of days consultation provided
<3,000	1	3	3	1	8
3,000–15,000	2	3	3	1	9
15,000–30,000	2	3	4	1	10
30,001–60,000	2	4	4	1	11
60,001–90,000	2	5	5	1	13
>90,000	2	5	6	1	14

Procedure for Requesting Consultation Services

Requests for consultation services for ship construction and renovation must be in writing and received at least 45 days prior to the requested travel dates. (See Appendix B for a sample request.)

Applicability

The inspection fees will be applicable to all passenger cruise vessels for which sanitation inspections are conducted as part of CDC's VSP. The construction and renovation fees will be applicable to all passenger cruise vessels for which CDC provides consultation on ship construction and renovations.

Dated: November 7, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

Appendix A

SIZE/COST FACTOR

Vessel size (GRT[1])	Average cost X
Extra Small (< 3,001)	0.25
Small (3,001–15,000)	0.50
Medium (15,001–30,000)	1.00
Large (30,001–60,000)	1.50
Extra Large (60,001—90,000)	2.00
Mega (>90,000)	2.50

FEE SCHEDULE JANUARY 1, 1998—SEPTEMBER 30, 1998

Vessel size (GRT[1])	Inspection[2]	Consultation
Extra Small (< 3,001)	$ 1,075	$ 3,225
Small (3,001–15,000)	$ 2,150	$ 6,450
Medium (15,001–30,000)	$ 4,300	$12,900
Large (30,001–60,000)	$ 6,450	$19,350
Extra Large (60,001–90,000	$ 8,600	$25,800
Mega (>90,000)	$10,750	$32,250

[1] GRT-Gross Register Tonnage in cubic feet, as shown in Lloyd's Register of Shipping.
[2] Inspections and reinspections involve the same procedure, require the same amount of time, and will, therefore, be charged at the same rate.

Appendix B

Sample

Fax to: Henry Falk, M.D., Director, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., (F28), Atlanta, GA 30341–3724 Facsimile (770) 488–4127

Fax copy to: Program Manager, Vessel Sanitation Program, Special Programs Group, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., (F16), Atlanta, GA 30341–3724, Facsimile (770) 488–4127

We request the presence of a DHHS representative for consultation on cruise liner (NAME). We tentatively expect to take delivery of the cruise liner on (DATE). We would like to schedule the consultation for (DATE). We expect the consultation to take approximately (NUMBER OF DAYS).

We will pay CDC in accordance with the consultation fee published in the **Federal Register**, and for all expenses in connection with the shipyard inspection. We will make all necessary arrangements for lodging and transportation, which includes airfare and ground transportation in (CITY, STATE, COUNTRY). We will provide in-kind for lodging and transportation expenses. All remaining expenses, such as en route per diem and meals and miscellaneous expenses, including ground transportation to and from the airport nearest the representatives work site or residence, should be sent to the following address:

Company
Attention:
Street Address
City, State, Country
Zip Code
Office Telephone Number
Facsimile Number

If you have questions regarding this confirmation, please contact:

Signed:

[FR Doc. 97–30056 Filed 11–14–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 97N–0263 and 87N–0262]

European Research Associates, Ltd. et al.; Withdrawal of Approval of Three New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of three new drug applications (NDA's). The basis for the withdrawals is that the holders of the applications have repeatedly failed to file required annual reports on these NDA's.

EFFECTIVE DATE: November 17, 1997.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs or antibiotics for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81).

In the **Federal Register** of July 10, 1997 (62 FR 37063), FDA offered an opportunity for a hearing on a proposal to withdraw approval of four NDA's because the firms had failed to submit the required annual reports for these NDA's.

The agency received one request for a hearing from Global Pharmaceutical Corp., Castor and Kensington Aves., Philadelphia, PA 19124–5694. Global has filed an annual report for NDA 9–273, Rauwolfia Serpentina Tablets, 50 and 100 milligram (mg). Therefore, approval of this NDA is not being withdrawn.

The holders of the other three applications did not respond to the notice of opportunity for hearing. Failure to file a written notice of participation and request for a hearing as required by 21 CFR 314.200 constitutes an election by the applicant not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and a waiver of any contentions concerning the legal status of the drug products. Therefore, the Director, Center for Drug Evaluation and Research, is withdrawing approval of the NDA's listed in the table in this document.

Application No.	Drug	Applicant
NDA 11–623	Mucilose Super Powder	European Research Associates, Ltd., Pailinakis Bldg., Elisabeth Ave., P.O. Box N3334, Nassau, N.P., Bahamas.
NDA 12–748	Duotrate (pentaerythritol tetranitrate) Capsules, 45 mg	Jones Medical Industries, Inc., 1945 Craig Rd., St. Louis, MO 63146.
NDA 16–470	Duotrate (pentaerythritol tetranitrate) Capsules, 30 mg	Do.

The last two products listed, NDA's 12–748 and 16–470, were named in a notice of opportunity for hearing published in the **Federal Register** of October 14, 1984 (49 FR 40213), proposing to withdraw the applications, along with other applicants' products, because they lack substantial evidence of effectiveness. In response to that notice, hearings were requested and a hearing was granted (52 FR 32170; August 26, 1987); Jones Medical, the