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

The average cost per inspection is multiplied by a size/cost factor to determine the fee for vessels in each size category. The size/cost factor was established in the proposed fee schedule published in the **Federal Register** on July 17, 1987 (52 FR 27060), and revised in a schedule published in the **Federal Register** on November 28, 1989 (54 FR 48942). The revised size/cost factor is presented in Appendix A.

Fee

The fee schedule is presented in Appendix A and will be effective October 1, 2002, through September 30, 2003. This fee schedule represents a 4.2 percent decrease over the current fee schedule, which became effective October 1, 2001. If travel expenses continue to increase, it may be necessary to readjust the fees before September 30, 2003, because travel comprises a sizable portion of the program's costs. 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.

Applicability

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

Dated: August 15, 2002.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention.

APPENDIX

Appendix A

SIZE/COST FACTOR

Vessel size	GRT [1]	Average cost
Extra Small	<3,001	0.25
Small	3,001–15,001	0.50
Medium	15,000–30,000	1.00
Large	30,001–60,000	1.50
Extra Large	>60,000	2.00

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

FEE SCHEDULE OCTOBER 1, 2002–SEPTEMBER 30, 2003

Vessel size	GRT [1]	Fee ($U.S.)
Extra small	<3,001	1,150
Small	3,001–15,001	2,300
Medium	15,001–30,000	4,600
Large	30,001–60,000	6,900
Extra large	>60,000	9,200

Note: Inspections and reinspections involve the same procedure, require the same amount of time, and are, therefore, charged at the same rate.

[FR Doc. 02–21249 Filed 8–20–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0350]

Draft Guidance for Industry on Handling and Retention of Bioavailability and Bioequivalence Testing Samples; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Handling and Retention of Bioavailability and Bioequivalence Testing Samples.'' Inspection of clinical and analytical sites that perform bioavailability (BA) and bioequivalence (BE) studies frequently reveals the absence of reserve samples at the testing facilities where the studies are conducted. The draft guidance is intended to clarify how to distribute test articles and reference standards to testing facilities, how to randomly select reserve samples, and how to retain reserve samples.

EFFECTIVE DATE: Submit written or electronic comments on the draft guidance by September 20, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Martin Yau, Center for Drug Evaluation and Research (HFD–45), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5458.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Handling and Retention of Bioavailability and Bioequivalence Testing Samples.'' Following the generic drug crisis in the 1980s, FDA issued regulations to deter possible bias and fraud in BA and BE testing by study sponsors and/or drug manufacturers (58 FR 25918, April 28, 1993). In the preamble of the final rule, the agency stated that the study sponsor should not separate out the reserve samples of the test article and reference standard prior to sending the drug product to the testing facility. This is to ensure that the reserve samples are in fact representative of the same batches provided by the study sponsor for the testing. FDA's Division of Scientific Investigations and field investigators from the Office of Regulatory Affairs conduct inspections of clinical and analytical sites that perform BA and BE studies for sponsors and/or drug manufacturers seeking approval of generic and new drug products. A frequent finding from these inspections is the absence of reserve samples at the testing facility. This draft guidance clarifies the responsibilities of the involved parties for retention of samples used in BA and BE studies. It includes recommendations for sampling techniques and responsibilities in various study settings.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on retention of BA and BE testing samples. It does not create or confer any rights for or on any person and does 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 Dockets Management Branch (see **ADDRESSES**) written comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: August 13, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02–21262 Filed 8–20–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0337]

Draft Guidance for Industry on Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation.'' This guidance provides recommendations to applicants on the chemistry, manufacturing, and controls (CMC); human pharmacokinetics and bioavailability; and labeling documentation for liposome drug products submitted in new drug applications (NDAs).

DATES: Submit written or electronic comments on the draft guidance by November 19, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Liang Zhou, Center for Drug Evaluation and Research (HFD–180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7471.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation.''

Liposome drug products are defined as drug products containing drug substances (active pharmaceutical ingredients) encapsulated in liposomes. A liposome is a microvesicle composed of a bilayer of lipid amphipathic molecules enclosing an aqueous compartment. Liposome drug products are formed when a liposome is used to encapsulate a drug substance within the lipid bilayer or in the interior aqueous space of the liposome. A drug substance in a liposome formulation is intended to exhibit a different pharmacokinetic and/or tissue distribution (PK/TD) profile from the same drug substance (or active moiety) in a nonliposomal formulation given by the same route of administration. The complete characterization of the PK/TD profile of a new liposome drug product is essential to establish the safe and effective dosing regimen of the product.

The guidance provides recommendations to applicants on the CMC, human pharmacokinetics and bioavailability, and labeling documentation for liposome drug products submitted in NDAs. The guidance does not provide recommendations on: (1) Clinical efficacy and safety studies, (2) nonclinical pharmacology and/or toxicology studies, (3) bioequivalence studies or those to document sameness, (4) liposomal formulations of vaccine adjuvants or biologics, or (5) drug-lipid complexes.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on liposome drug products: CMC, human pharmacokinetics and bioavailability, and labeling documentation. It does not create or confer any rights for or on any person and does 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 Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: August 13, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02–21263 Filed 8–20–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Rural Assistance Center

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration announces up to $600,000 in FY 2002 funds is available to fund a single competitive