

**Sandra L. Kusumoto,**

*Director, Bureau of Consumer Complaints and Licensing.*

[FR Doc. 02-2271 Filed 1-30-02; 8:45 am]

BILLING CODE 6730-01-P

## FEDERAL MARITIME COMMISSION

### Ocean Transportation Intermediary License; Applicant

Notice is hereby given that the following applicant has filed with the Federal Maritime Commission an application for license as Non-Vessel Operating Common Carrier and Ocean Freight Forwarder—Ocean Transportation Intermediary pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. app. 1718 and 46 CFR 515).

Persons knowing of any reason why the following applicant should not receive a license are requested to contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573.

Non-Vessel Operating Common Carrier Ocean Transportation Intermediary Applicant:

Security Storage Company of Washington, 1701 Florida Avenue, NW., Washington, DC 20009-1697, Officers: Larry DePace, Senior Vice President (Qualifying Individual), Charles R. Lawrence, President/CEO.

Dated: January 25, 2002.

**Bryant L. VanBrakle,**

*Secretary.*

[FR Doc. 02-2272 Filed 1-30-02; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01D-0584]

#### Draft “Guidance for Industry: Use of Nucleic Acid Tests on Pooled Samples From Source Plasma Donors to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV”; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled “Guidance for Industry: Use of Nucleic Acid Tests on Pooled Samples From Source Plasma Donors to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV” dated

December 2001. The draft guidance document, when finalized, would inform all establishments that manufacture Source Plasma that FDA has approved nucleic acid tests (NAT) to identify human immunodeficiency virus type 1 (HIV-1) and hepatitis C virus (HCV) in Source Plasma donations. The draft document recommends that manufacturers submit a prior approval supplement to a biologics license application (BLA) to implement HIV-1 and HCV NAT by a specified date.

**DATES:** Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by May 1, 2002.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 Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document 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>.

**FOR FURTHER INFORMATION CONTACT:** Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft document entitled “Guidance for Industry: Use of Nucleic Acid Tests on Pooled Samples From Source Plasma Donors to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV” dated December 2001. FDA’s final rule (66 FR 31146, June 11, 2001) entitled “Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Diseases” became

effective on December 10, 2001. The provision in 21 CFR 610.40(b) of the rule provides that manufacturers “must perform one or more screening tests to adequately and appropriately reduce the risk of transmission of communicable disease agents” (66 FR 31146 at 31162). As we noted in the preamble to the final rule, the standard for adequate and appropriate testing will change as new testing technology is approved by FDA. We explained, “we intend to regularly issue guidance describing those tests that we believe would adequately and appropriately reduce the risk of transmission of communicable disease agents” (66 FR 31146 at 31149).

The availability of NAT to identify HIV-1 and HCV will change the testing protocol that should be used to adequately and appropriately reduce the risk of transmission of those diseases. The draft document recommends that manufacturers submit a prior approval supplement to a BLA to implement HIV-1 and HCV NAT by a specified date.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). This draft guidance document represents the agency’s current thinking on this topic. 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 requirement of the applicable statutes and regulations.

##### II. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by May 1, 2002. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document 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/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: January 23, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-2321 Filed 1-30-02; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget under the Paperwork Reduction Act of 1995. To request more information on the proposed project or

to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

*Comments are invited on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

#### **Proposed Project: The National Health Service Corps (NHSC), Professional Training and Information Questionnaire (PTIQ), (OMB No. 0915-0208)—Revision**

The National Health Service Corps (NHSC) of the HRSA's Bureau of Health Professions (BHP), is committed to improving the health of the Nation's underserved by uniting communities in need with caring health professionals

and by supporting communities' efforts to build better systems of care.

The National Health Service Corps (authorized by the Public Health Services Act, section 331) collects data on its programs to ensure compliance with legislative mandates and to report to Congress and policymakers on program accomplishments. To meet these objectives, the NHSC requires a core set of information collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends.

The PTIQ is used to collect data related to professional issues from NHSC obligated Scholarship Program Recipients including physicians, physician assistants (PAs), nurse practitioners (NPs), certified nurse midwives (CNMs), and other disciplines in the current year's placement cycle. This data is used to match an individual health care professional with the most appropriate clinical practice setting.

The PTIQ will be mailed twelve months in advance of the intended service availability date. Estimates of annualized reporting burden are as follows:

Type of respondent	Number of respondents	Responses per respondent	Hours per response (minutes)	Total burden hours
Health Care Professionals .....	311	1	5	26

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 11-05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 25, 2002.

**Jane M. Harrison,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. 02-2296 Filed 1-31-02; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Comment Request

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*Comments are invited on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

#### **Proposed Project: National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Regulations and Forms (OMB No. 0915-0126)—Revision**

The National Practitioner Data Bank (NPDB) was established through Title IV of Public Law 99-660, the Health Care Quality Improvement Act of 1986, as amended. Final regulations governing the NPDB are codified at 45 CFR part 60. Responsibility for NPDB implementation and operation resides in the Bureau of Health Professions, Health Resources and Services Administration, U.S. Department of Health and Human Services (DHHS). The NPDB began operation on September 1, 1990.

The intent of Title IV of Public Law 99-660 is to improve the quality of health care by encouraging hospitals, State licensing boards, professional societies, and other entities providing health care services, to identify and discipline those who engage in unprofessional behavior; and to restrict the ability of incompetent physicians, dentists, and other health care practitioners to move from State to State