HIV–1, HIV–2, hepatitis B virus, hepatitis C virus, HTLV-I, HTLV-II, and Treponema palladum. A request for determination may be based upon infectious agent tests performed using test kits other than those licensed or approved by FDA. In such cases, FDA suggests that the request contain a copy of the labeling for the test kit used, translated into English, as part of the submission; and

• A copy of the product's label. FDA recommends that the label include information such as the product's descriptive name; the name(s) and address(es) of establishments collecting, preparing, labeling, or pooling the source material; donor, lot, or pool numbers relating the unit to the donor; the recommended storage temperature (in degrees Celsius); the product's quantity; statements such as ''Import for Export,'' ''Not for Use in Products Subject to Licensure Under Section 351 of the Public Health Service Act,'' and ''For Manufacturing Use Only'' or ''For Manufacturing into Noninjectable Products Only;'' statements indicating that the product has been tested for infectious disease agents and, if the product has tested positive for an infectious disease agent, the term ''BIOHAZARD'' as well as any other appropriate warnings or special handling instructions.

A request for determination may be sent to the Center for Biologics Evaluation and Research, Office of Compliance, Division of Case Management (HFM–610), 1401 Rockville Pike, Rockville, MD 20852–1448. If FDA determines that the blood, blood component, source plasma, or source leukocyte, or a component, accessory, or part meets the appropriate circumstances and conditions to permit its importation into the United States, FDA will notify the person requesting the determination that it has granted permission to import the article.

XII. For Further Information Contact:

For animal drugs: Drugs Team, Division of Compliance, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1785.

For biologics: Division of Case Management (HFM–610), Office of Compliance, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, rm. 200N, Rockville, MD 20852–1448, 301–827–6201.

For devices: Division of Program Operations (HFZ–305), Center for Devices and Radiological Health, Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4699.

For drugs: Division of Labeling and Nonprescription Drug Compliance (HFD–310), Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855–2737, 301–594–0063.

For drugs exported for investigational use under § 312.110: Office of International Affairs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4480.

For food additives, color additives, and dietary supplements: Office of Field Programs (HFS–602), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4187.

These offices may have additional guidance documents and information on specific export topics or products.

For general policy questions: Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3344.

Dated: June 2, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration.

[Document Identifier: HCFA–724]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Medicare/Medicaid Psychiatric Hospital Survey Data and Supporting Regulations Contained in 42 CFR 482.60, 482.61 and 482.62; *Form No.:* HCFA–724 (OMB# 0938–0378); *Use:* The information collected on this form will assist HCFA in maintaining an accurate data base on providers participating in the Medicare psychiatric hospital program. The HCFA–724 has two parts; part one is completed by the facility (i.e., location, number of beds, number of admissions) and part two is completed by the survey team (i.e, dates of survey, type of survey, survey team composition); *Frequency:* Annually; *Affected Public:* Federal government, Business or other for-profit, Not-for-profit institutions, and State, local or tribal government; *Number of Respondents:* 350; *Total Annual Responses:* 350; *Total Annual Hours:* 175.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: June 2, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

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