intend to modify their device and are in the process of deciding the type of documentation and/or submission necessary for that particular modification. The draft guidance concerning changes to an existing device is intended to complement, not supplant, existing guidances on the premarket approval process. It is not intended to apply to combination products, such as drug/device or biologic/device combinations.

This draft guidance incorporates three separate flowcharts for in vitro diagnostic devices (IVD's). These flowcharts cover changes in technology or performance, change assessment, and materials changes for IVD's. This draft guidance applies to in vitro diagnostic devices regulated by the CDRH and application of this guidance to in vitro diagnostic devices regulated under premarket approval by the Center for Biologics Evaluation and Research (CBER) should be discussed with CBER.

The types of modifications addressed in the draft guidance include changes in device design, device labeling, device materials, and the manufacturing process for the device. This draft guidance can also be applied to situations when a legally marketed device is the subject of a recall and a change is indicated to assure the safety and effectiveness of the device.

When contemplating changes to any approved device, PMA holders should use the flowchart for ''each'' type of proposed change. In those circumstances where the proposed change is not addressed in the flowchart or in a device-specific guidance document, PMA holders are encouraged to contact the Office of Device Evaluation (ODE) in CDRH for additional information.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on modifications to devices which are subject to premarket approval. This draft guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public.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 applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Modifications To Devices Subject To Premarket Approval—The PMA Supplement Decision Making Process'' via your fax machine, call the CDRH Facts–On–Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (855) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes ''Modifications To Devices Subject To Premarket Approval—The PMA Supplement Decision Making Process,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

IV. Comments

Interested persons may, on or before November 4, 1998, submit to Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any 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 document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 22, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–20958 Filed 8–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–2567]

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: Statement of Deficiencies and Plan of Correction and Supporting Regulations in 42 CFR 488.18, 488.26, and 488.28; Form No.: HCFA–2567 (OMB# 0938–0391); Use: This Paperwork package provides information regarding the form used by the Medicare, Medicaid, and the Clinical Laboratory Improvement Amendments (CLIA) programs to document a health care facility's compliance or noncompliance (deficiencies) with regard to the Medicare/Medicaid Conditions of Participation and Coverage, the requirements for participation for Skilled Nursing Facilities and Nursing Facilities, and for certification under

CLIA. This form becomes the evidentiary basis for HCFA certification decisions (including termination or denial of participation), and the form of public disclosure; Frequency: Biennially and Annually; Affected Public: Business or other for-profit, Not-for-profit institutions, Federal Government, and State, local or tribal government; Number of Respondents: 60,000; Total Annual Responses: 60,000; Total Annual Hours: 120,000.

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: July 31, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 98–21047 Filed 8–5–98; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–2030–N]

RIN 0938–AJ13

Medicaid Program; Decision on Funding for the AIDS Healthcare Foundation START Program

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the award of a grant in the sum of $1 million to the AIDS Healthcare Foundation of Los Angeles for a demonstration project entitled, ''START PROGRAM: Success Through Anti-Retroviral Therapy.''

FOR FURTHER INFORMATION CONTACT: Wayne Smith, Ph.D., Center for Medicaid and State Operations, (410) 786–6762.

SUPPLEMENTARY INFORMATION: This award is made based on language in H.R. Conf. Rept. 105–390 at 86 (1997) attendant to our agency's administrative budget authorization for Fiscal Year 1998 that directed us to devote ''$1,000,000 within research to conduct a demonstration of residential treatment facilities at the AIDS Healthcare Foundation in Los Angeles.''

The START program is a 4- to 6-week residential program designed to increase the ''adherence'' to HIV and AIDS medication regiments of individuals at high risk for non-adherence, or a history of non-adherence. The goals of the program are: (1) To educate participants and influence positive ''medication-taking'' habits and behaviors whereby they internalize successful treatment adherence strategies, (2) to assist participants in achieving and maintaining long term adherence, (3) to monitor and reinforce participants' success by analyzing viral load and CD4 counts, and (4) to provide ancillary support to assure successful compliance.

The purpose of this grant is to demonstrate how compliance with the complicated medication regimen for people living with HIV and AIDS who are at high risk of noncompliance can be increased by a short-term residential treatment program. The START program provides these individuals with a sheltered, structured environment in which the regimen can be established and residents can be counseled and supported.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 30, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 98–20953 Filed 7–31–98; 4:30 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection Renewal to be Submitted to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Information collection; correction.

SUMMARY: The U.S. Fish and Wildlife Service published a document in the **Federal Register** of July 28, 1998, concerning the submission of an information collection renewal to the Office of Management and Budget (OMB) for approval under the provisions of the Paperwork Reduction Act. The document contained incorrect information concerning coverage of the information collections by the Privacy Act.

FOR FURTHER INFORMATION CONTACT: Rebecca A. Mullin at (703) 358–2287, or electronically to rmullin@fws.gov.

Correction

In the **Federal Register** issue of July 28, 1998 (63 FR 40303), on page 40305, in the first column, correct the last sentence of the first paragraph to read:

The information collections in this program will be part of a system of record covered by the Privacy Act (5 U.S.C. 552(a)).

Dated: July 29, 1998.

Daniel M. Ashe,

Assistant Director for Refuges and Wildlife.

[FR Doc. 98–20916 Filed 8–5–98; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Intent to Prepare Comprehensive Conservation Plans

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of intent to prepare Comprehensive Conservation Plans.

SUMMARY: This notice advises that the Fish and Wildlife Service intends to gather information necessary to prepare Comprehensive Conservation Plans and associated environmental documents for Medicine Lake National Wildlife Refuge Complex in northeastern Montana, Red Rock Lakes National Wildlife Refuge in southwestern Montana, and Crescent Lake and North Platte National Wildlife Refuges in western Nebraska. The Medicine Lake NWR Complex includes the Medicine Lake National Wildlife Refuge, Lamesteer National Wildlife Refuge, and the Northeast Montana Wetland Management District. The Service is furnishing this Notice in compliance with Service CCP policy to advise other agencies and the public of its intentions and to obtain suggestions and information on the scope of issues to be considered in the planning process.

DATES: Written comments should be received by September 8, 1998.