premarket clearance for convenience kits that have intended uses, components, and processing methods that are described in the guidance, and where the assembler/manufacturer is able to reasonably conclude that any further processing of the kit and its components does not significantly affect the safety or effectiveness of any of its components. The intent to exercise enforcement discretion means that FDA does not intend to take enforcement action for the failure to submit premarket notification for convenience kits described in the guidance. In the future, FDA intends to propose rulemaking to formally exempt these types of kits from the requirement of premarket notification.

This guidance is effective immediately.

The ''Convenience Kits Interim Regulatory Guidance'' represents the agency's current thinking on premarket notification regulatory strategy for convenience kits. 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 statute, regulations, or both.

II. Electronic Access

In order to receive the ''Convenience Kits Interim Regulatory Guidance'' document 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 the second voice prompt press 2, and then enter the document number 562 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may do so by using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. The CDRH home page is updated on a regular basis and includes the ''Convenience Kits Interim Regulatory Guidance'' document, 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''. The ''Convenience Kits Interim Regulatory Guidance'' is available on the medical device reporting page at ''http://www.fda.gov/cdrh/ode/convkit.html''.

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.

III. Request for Comments

Interested persons may, at any time, submit to the contact person listed above written comments regarding this guidance.

Dated: August 21, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–22855 Filed 8–27–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–R–39]

Agency Information Collection Activities: Proposed Collection; Comment Request

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 the 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.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Home Health Medicare Conditions of Participation (COP) Information Collection Requirements (ICR's) as outlined in Regulation 42 CFR Part 484; *Form No.:* HCFA–R–39 OMB #0938–0365; *Use:* The ICR's contained in 42 CFR part 484 outline Home Health Agencies Medicare COP's to ensure Home Health Agencies meet Federal patient health and safety requirements. *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions and Federal Government; *Number of Respondents:* 10,203; *Total Annual Responses:* 10,203; *Total Annual Hours:* 86,008.

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection for which approval has expired; *Title of Information Collection:* Negative Case Action Review Process (NCA)/Annual Report and Supporting Regulations 42 CFR 431.800; *Form No.:* HCFA—6401 OMB #0938–0300; *Use:* HCFA uses the NCA reviews conducted by states to assure that beneficiaries are not being denied medical assistance that they are eligible for and that recipients are being given adequate and timely notice of termination. The results of NCA reviews are used by states and the Federal Government to identify problem areas and plan corrective action initiatives. *Frequency:* Annually; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 51; *Total Annual Responses:* 51; *Total Annual Hours:* 6,770.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, 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 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 20, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.

[FR Doc. 97–22963 Filed 8–27–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–R–207]

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

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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the 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: New Collection; *Title of Information Collection:* Evaluation of Five State Health Care Reform Demonstrations and the Evaluation of the Medicaid State Health Reform Demonstrations; *Form No.:* HCFA–R–207; *Use:* These evaluations will investigate health care reform in ten states that will implement or have implemented demonstration programs using Medicaid Section 1115 waivers. The surveys will gather information to answer questions regarding access to health care, quality of care delivered, satisfaction with health services, and the use and cost of health services. The surveys will be administered to Medicaid eligible and newly covered enrollees and eligible and near-eligible non-enrollees. A subsample of survey respondents will be SSI recipients and other disabled people who have participated in demonstrations for at least a year. Quality of care surveys will be administered to Medicaid enrollees who have diabetes and to parents of children in the Medicaid program who have pediatric asthma. *Frequency:* (Other) one time for most respondents; *Affected Public:* Individuals or Households; *Number of Respondents:* 33,693; *Total Annual Responses:* 34,035; *Total Annual Hours:* 10,279.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, 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 HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: August 11, 1997.

John P. Burke III,

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

[FR Doc. 97–22964 Filed 8–27–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*):

Applicant: Life Fellowship Bird Sanctuary, Seffner, FL, PRT–832609.

The applicant requests a permit authorizing import of 36 Galapagos tortoises (*Geochelone elephantopus*) from the Bermuda Aquarium, Natural History Museum and Zoo, Flatts, Bermuda for the purpose of enhancement of the species through captive propagation.

Applicant: University of Wisconsin, Dept. of Zoology, Madison, WI, PRT–831689.

The applicant request a permit to import blood and feather samples taken from captive-held Andean condors (*Vultur gryphus*) in Ecuador, Bolivia, Colombia, and Argentina for the purpose of scientific research.

Applicant: Cohanzick Zoo, Bridgeton, NJ, PRT–833281.

The applicant request a permit to import a male and female Bengal tigers (*Panthera tigris tigris*) born in captivity from Parken Zoo, Eskilstuna, Sweden, for the purpose of enhancement of the species through conservation education.

Applicant: University of Puerto Rico, Rio Piedras, PR, PRT–833581.

The applicant requests a permit to export and re-import non-living museum specimens of endangered and threatened species of plants and animals previously accessioned into the permittee's collection for scientific research. This notification covers activities conducted by the applicant for a five year period.

Applicant: Stephen Fullmer, Salt Lake City, UT, PRT–833360.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcas*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Written data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, Room 430, Arlington, Virginia 22203 and must be received by the Director within 30 days of the date of this publication.

The public is invited to comment on the following application(s) for permits to conduct certain activities with marine mammals. The application(s) was/were submitted to satisfy requirements of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*) and the regulations governing marine mammals (50 CFR 18).

Applicant: Richard Nelson, Sarasota, FL, PRT–833155.

The applicant requests a permit to import a polar bear (*Ursus maritimus*) sport-hunted prior to April 30, 1994 from the Foxe Basin polar bear population, Northwest Territories, Canada for personal use.

Applicant: Arlo Spiess, El Macero, CA, PRT–833156.

The applicant requests a permit to import a polar bear (*Ursus maritimus*) sport-hunted prior to April 30, 1994, from the Lancaster Sound polar bear population, Northwest Territories, Canada for personal use.

Applicant: John Richardson, New Middletown, OH, PRT–832321.

The applicant requests a permit to import a polar bear (*Ursus maritimus*) sport-hunted from the McClintock Channel polar bear population,