

This draft guidance identifies the types of applications that can be submitted under section 505(b)(2) of the act. A section 505(b)(2) application is an NDA submitted under section 505(b)(1) of the act and approved under section 505(c) of the act. This draft guidance also provides further information and amplification of information stated at 21 CFR 314.54.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on section 505(b)(2) applications. 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, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). 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 The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 30, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-0283]

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: New collection; Title of Information Collection: Market Survey of Fraud, Waste and Abuse Detection Software; *Form No.:* HCFA-R-0283 (OMB # 0938—new); *Use:* This information collection tool is essential to providing the Health Care Financing Administration (HCFA) a vehicle to ascertain cutting edge fraud, waste, and abuse detection products. HCFA and its contractors presently use a number of these tools, as do other segments of government, the health care industry, and industry generally. New products taking advantage of new technologies are in continuous development. This completely voluntary survey will ensure that HCFA is vigilant in identifying new advances to help fight the scourge of Medicare fraud and abuse.; *Frequency:* Annually; *Affected Public:* Business or other for profit, and Not for profit institutions; *Number of Respondents:* 400; *Total Annual Responses:* 450; *Total Annual Hours:* 1,350.

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/prduct95.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: October 26, 1999.

John P. Burke III,

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

[FR Doc. 99-31703 Filed 12-7-99; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Application for Approval

The following applicant has applied for approval to conduct certain activities with birds that are protected under the Wild Bird Conservation Act of 1992. This notice is provided under Section 112, paragraph 4, of the Wild Bird Conservation Act of 1992, and Title 50, of the Code of Federal Regulations, § 15.26(c).

Applicant: Jerry Jennings, Fallbrook, CA, on behalf of the Cooperative Breeding Program for Keel-billed toucan, Red-breasted toucan, Saffron toucanet, and Chestnut-eared aracari (CB006). The applicant wishes to amend the approved cooperative breeding program to include the Ariel toucan (*Ramphastos vitellinus ariel*), Channel-bill toucan (*Ramphastos vitellinus vitellinus*), Couvier's toucan (*Ramphastos tucanus couvieri*), and the Toco toucan (*Ramphastos toco*). The Toucan Preservation Center maintains the responsibility for the oversight of the program.

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 700, Arlington, Virginia 22203 and must be received by the Director within 30 days of the date of this publication.

Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of these documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203. Phone: (703/358-2095); FAX: (703/358-2298).

Dated: December 2, 1999.

Andrea Gaski,

Acting Chief, Branch of Operations, Office of Management Authority.

[FR Doc. 99-31762 Filed 12-7-99; 8:45 am]

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