

guidance document began in March 1999.

## II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the final regulations implementing the MQSA. The draft guidance is not final nor is it in effect at this time. 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 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 "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3" 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 (1496) 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Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH Home Page includes "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document # 3," 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>. "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document # 3" will be available at <http://www.fda.gov/cdrh/mammography>.

## IV. Comments

Interested persons may, on or before March 8, 2000, submit to Dockets Management Branch (address above) written comments regarding this draft guidance.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 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: November 24, 1999.

**Linda S. Kahan,**

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

[FR Doc. 99-31777 Filed 12-7-99; 8:45 am]

**BILLING CODE 4160-01-F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99D-4809]

#### Draft Guidance for Industry on Applications Covered by Section 505(b)(2); Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Applications Covered by Section 505(b)(2)." A section 505(b)(2) application is a new drug application (NDA) for which one or more of the investigations relied upon by the applicant for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This draft guidance also provides information on procedures for submitting an application for approval of a change from an approved drug. **DATES:** Written comments on the draft guidance may be submitted by February 7, 2000. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and

Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Khyati N. Roberts, Center for Drug Evaluation and Research (HFD-6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-6779.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance for industry entitled "Applications Covered by Section 505(b)(2)." Section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) describes three types of NDA's: (1) An application that contains full reports of investigations of safety and effectiveness (section 505(b)(1) of the act); (2) an application that contains full reports of investigations of safety and effectiveness but where at least one of those reports required for approval was not conducted by or for the applicant or for which the applicant has not obtained a right of reference (section 505(b)(2) of the act); or (3) an application that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, as a previously approved product (section 505(j) of the act).

Section 505(b)(2) of the act was added to the act by the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman amendments). It explicitly allows FDA to rely, for approval of an NDA, on data not developed by the applicant. Section 505(b)(2) and (j) of the act replaced FDA's paper NDA policy, which had permitted an applicant to rely on studies published in the scientific literature to demonstrate the safety and effectiveness of duplicates of certain post-1962 pioneer drug products (46 FR 27396, May 19, 1981). Enactment of the generic drug approval provision of the Hatch-Waxman amendments ended the need for approvals of duplicate drugs through the paper NDA process. Specifically, section 505(j) of the act allows for approval of duplicates of approved NDA's on the basis of chemistry and bioequivalence data. Section 505(b)(2) of the act allows for approval of applications other than those for duplicate products.

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.*

[FR Doc. 99-31698 Filed 12-7-99; 8:45 am]

**BILLING CODE 4160-01-F**

## 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/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto: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]

**BILLING CODE 4120-03-P**

## 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]

**BILLING CODE 4310-55-P**