anticipated cost and timeline for market entry?

III. Submission of Comments

All comments submitted to the public docket are public information and may be posted to FDA's Web site at: *http://www.fda.gov* for public viewing. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be reviewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 12, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–11365 Filed 5–19–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0468]

Guidance for Industry on the Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance for industry (#122) entitled ''Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores.'' The purpose of this document is to provide guidance on the manufacture and labeling of foods that contain raw meat, or other raw animal tissues, for consumption by dogs, cats, other companion or pet animals, and captive noncompanion animal carnivores and omnivores.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the guidance document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the guidance document and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: William Burkholder, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0179, e-mail: *William.burkholder@fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 18, 2002 (67 FR 77500), FDA published a notice of availability for a draft guidance entitled ''Draft Guidance for Industry on Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores.'' FDA gave interested persons until March 3, 2003, to comment. FDA considered all comments received and, where appropriate, incorporated them into the guidance.

II. Paperwork Reduction Act of 1995

According to the Paperwork Reduction Act of 1995, a collection of information should display a valid OMB control number. This guidance contains no collections of information.

III. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking about the manufacture and labeling of raw meat foods for companion and captive noncompanion carnivores and omnivores. It does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

IV. Comments

As with all of FDA's guidance, the public is encouraged to submit written or electronic comments on this guidance. FDA periodically will review the comments in the docket and, where appropriate, will amend the guidance.

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Electronic comments may be submitted on the Internet at *http://www.fda.gov/dockets/ecomments*. Once on this site, select [2002D–0468] ''Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores'' and follow the directions. Copies of this guidance may be obtained on the Internet at *http://www.fda.gov/cvm/guidance/published.htm*.

Dated: May 12, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–11366 Filed 5–19–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Guidance and Forms for the Title V Section 510 Abstinence Education Grant Program Application/Annual Report—NEW

The Application Guidance for Section 510 of the Social Security Act is used annually by all States and jurisdictions in applying for Abstinence Education Block Grants under Section 510 of Title

V of the Social Security Act, and in preparing the required annual report. This guidance provides guidelines to the State Maternal and Child Health Agencies (MCH) on how to apply for the appropriated Section 510 Abstinence Education funds.

The Section 510 Abstinence Education Grant program enables States to provide abstinence education, and at the option of States, where appropriate, mentoring, counseling, and adult supervision to promote abstinence from sexual activity, with a focus on those groups most likely to bear children out-of-wedlock. Projects must meet the legislative requirements as provided in Section 510 of Title V of the Social Security Act. State agencies funded under the program are required to report annually on four national performance measures and a minimum of two State-developed performance measures.

The guidance used annually by the 47 States and 4 jurisdictions that have applied for and received Section 510 Abstinence Education Grant funding have an estimated average burden of 170 hours. The burden estimate for this activity is based upon information provided by the pilot States as well as previous experience by States in completing the application. The estimated response burden is as follows:

Application and report	Number of respondents	Responses per respondent	Total responses	Burden hours per response	Total burden hours
States and Jurisdictions	51	1	51	170	8,670

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Desk Officer, Health Resources and Services Administration, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 14, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–11367 Filed 5–19–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Border and Transportation Security Directorate

Submission for Review; Extension of Currently Approved Information Collection Requests for United States Visitor and Immigrant Status Indicator Technology Program (US–VISIT)

AGENCY: Border and Transportation Security Directorate, DHS.

ACTION: Notice; 30-day notice of information collections under review.

SUMMARY: The Department of Homeland Security (DHS) has submitted the following information collection request (ICR) 1600–0006 to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on January 5, 2004, at 69 FR 479, allowing for OMB review and a 60-day public comment period. Comments received by DHS are being reviewed as applicable. The purpose of this notice is to allow an additional 30 days for public comments on the information collections under review.

DATES: Comments are encouraged and will be accepted until June 21, 2004.

ADDRESSES: Written comments and/or suggestions regarding the items contained in this notice should be directed to Desk Officer for Homeland Security, Room 10235, Office of Management and Budget, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Steve Yonkers, Privacy Officer, US–VISIT, (202) 298–5200 (this is not a toll free number).

SUPPLEMENTARY INFORMATION: This process is conducted in accordance with 5 CFR 1320.10. A copy of this ICR, with applicable supporting documentation, may be obtained by calling the Paperwork Reduction Act Contact listed above. The Office of Management and Budget is particularly interested in comments which:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

Analysis

Agency: Border and Transportation Security Directorate, Department of Homeland Security.

Title: United States Visitor and Immigrant Status Indicator Technology Program (US–VISIT).

Title of Form: No form. Collection of biometrics will be in electronic or photographic format.

OMB Number: 1600–0006.

Frequency: On occasion.

Affected Public: Individual aliens. Non-immigrant visa holders who seek admission to the United States at air and sea ports of entry and designated departure locations.

Estimate Number of Respondents: From January 5, 2004, to January 5, 2005, the number of nonimmigrant visa-holders required to provide biometrics at the air and sea ports of entry is anticipated to be approximately 24 million, comprised of approximately 19.3 million air travelers and 4.5 million sea travelers.

Estimated Time per Respondent: The average processing time per person for whom biometrics will be collected is approximately one minute and fifteen seconds at entry, with 15 seconds being the additional time added for biometric collection over and above the normal inspection processing time. The average additional processing time upon exit is estimated at one minute per person. There are no additional fees for traveling aliens to pay.

Estimated Burden Hours: Approximately 100,800.

Total Burden Cost (Capital/Startup): None.

Total Burden Cost (Operating/Maintaining): None.

Description: The biometric information to be collected is for nonimmigrant visa holders who seek admission to the United States at the air and sea ports of entry, and certain