

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.*

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## 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](mailto: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.*

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## 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