

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0468]

DMR

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Certifier D. Hawkins

Draft Guidance for Industry on Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry (#122) entitled "Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores." This draft guidance document is intended to provide specific guidance on the manufacture and labeling of foods that contain raw meat, or other raw animal tissues, for consumption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DATES: Submit written or electronic comments on the draft guidance by [*insert date 75 days after date of publication in the Federal Register*], to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.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

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your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 Comments should be identified with the full title of the draft guidance document and the docket number found in brackets in the heading of this document.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: bburkhol@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Commercial foods for carnivorous and omnivorous animals containing raw meat, or other raw animal tissues, have been on the market for many years for use by zoos, mink farms, dog-racing facilities, and other professional establishments. Some of these products have included meat and other tissues from mammals and poultry that have died other than from slaughter or have otherwise been unfit for human consumption. Products containing such tissues are adulterated under section 402(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)). However, FDA's Compliance Policy Guide 7126.23 provides that investigation should only be conducted as a followup to complaints or reports of injuries. When raw meat or raw animal tissues were purchased and used by zoos, mink farms, dog-racing facilities, or other professional establishments, there was a presumption that the purchaser was

aware of the potential food safety and nutritional deficiency risks of using such products. However, the new trend is toward use of raw meat foods by pet owners and others who may not be as aware of the potential harm.

FDA does not believe that raw meat foods are consistent with the goal of protecting the public from significant health risks, particularly when such products are brought into the home and/or used to feed domestic pets. Objective data derived specifically from commercial raw meat pet foods are sparse for quantifying the magnitude of risk to public health from such products. However, the potential for risk to public health from such products is undeniable, and the magnitude of such risk is likely significant given the microbiological results from studies of ingredients that could compose such products and the limited sampling of commercial raw pet foods themselves. Therefore, for firms choosing to manufacture and market raw meat and raw animal tissue products, more specific guidance for industry is warranted for how such products could be manufactured and labeled to protect pet owners and pets from risks involving food safety and nutritional deficiency.

II. Significance of Guidance

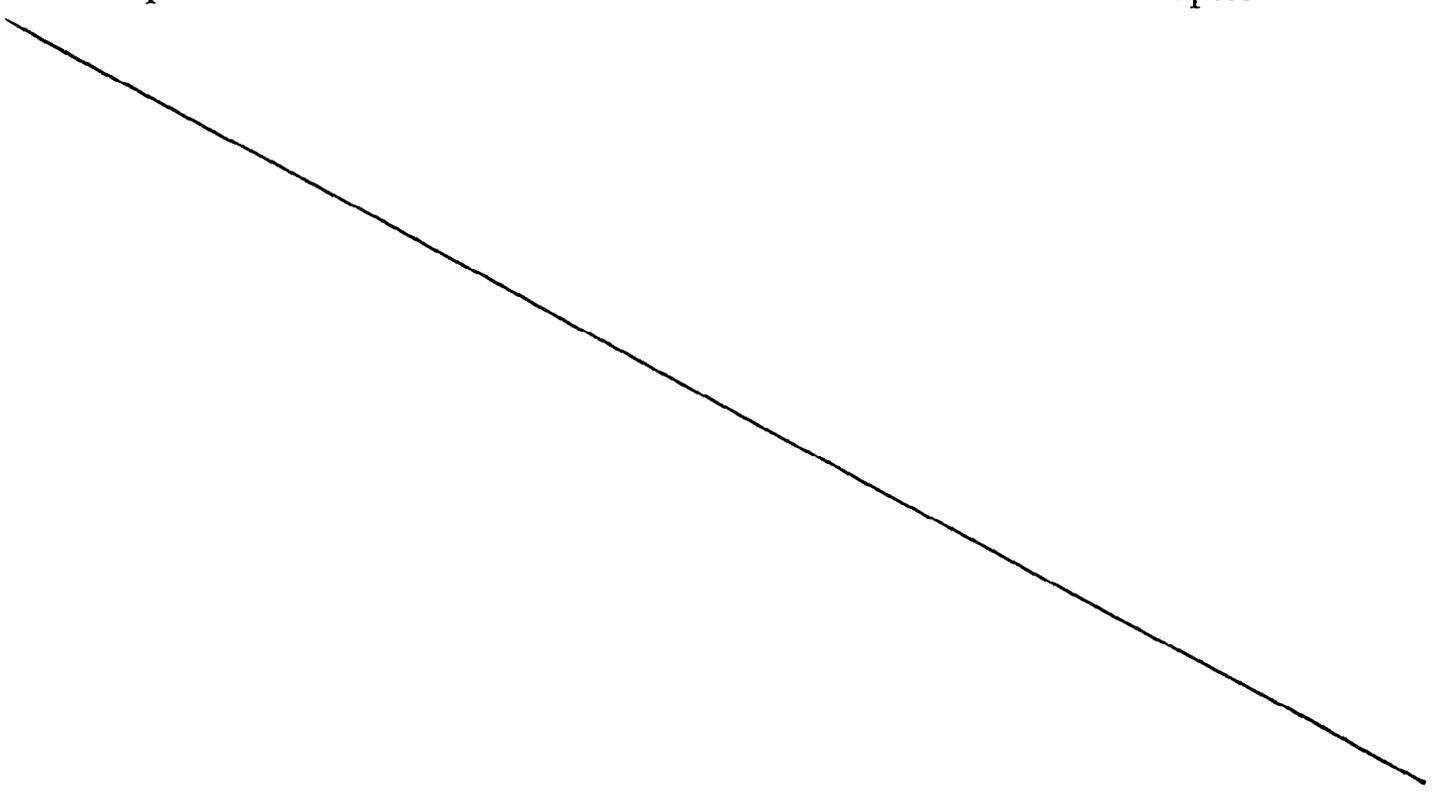
This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking about the manufacture and labeling of raw meat foods for companion and captive noncompanion carnivores and omnivores. It does not create or confer any rights for or on any person and 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 and regulations.

III. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this draft guidance document. Two copies of mailed 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 are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

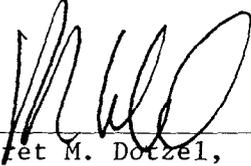
IV. Electronic Access

Electronic comments may be submitted on the Internet at <http://www.fda.gov/dockets/ecomments>. Once on this site, select “02D–0468—Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores” and follow the directions. Copies



of this draft guidance may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm>.

Dated: 12/8/02
December 8, 2002.



Margaret M. Dotzel,
Assistant Commissioner for Policy.

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Dawn P. Hawkins