

requires 4 percent). The test product meets all the requirements of the standard with the exception of these deviations.

On April 19, 2002, Kraft Foods, Inc., requested that its temporary permit be extended to allow for additional time for the market testing of its products under the permit in order to gain additional information in support of the petition to amend the standard for salad dressing. The petitioner requests FDA to revise, simplify, and modernize the standard for salad dressing.

The agency finds that it is in the interest of consumers to issue an extension of the time period for the market testing of products identified as salad dressing to gain information on consumer expectations and acceptance. FDA is inviting interested persons to participate in the market test under the conditions that apply to Kraft Foods, Inc. (e.g., the composition of the test product), except for the designated area of distribution. Any person who wishes to participate in the extended market test must notify, in writing, the Team Leader, Conventional Foods Team, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS-822), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. The notification must include a description of the test products to be distributed, justification for the amount requested, the area of distribution, and the labeling that will be used for the test product (i.e., a draft label for each size of container and each brand of product to be market tested). The information panel of the label must bear nutrition labeling in accordance with 21 CFR 101.9. Each of the ingredients used in the food must be declared on the label as required by the applicable sections of 21 CFR part 101.

Therefore, under the provisions of § 130.17(i), FDA is extending the temporary permit granted to Kraft Foods, Inc., Three Lakes Dr., Northfield, IL 60093-2753 to provide for continued market testing of 150 million pounds of product on an annual basis. The test products will bear the name "salad dressing." FDA is extending the expiration date of the permit so that the permit expires either on the effective date of a final rule amending the standard of identity for salad dressing that may result from the petition or 30 days after denial of the petition, whichever ever the case may be. All other conditions and terms of this permit remain the same.

Dated: December 9, 2002.

**Christine Taylor,**

*Director, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. 02D-0468]**

#### **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 March 3, 2003, 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 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/comments>. 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](mailto: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: December 8, 2002.

**Margaret M. Dotzel,**

*Assistant Commissioner for Policy.*

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**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 (OMB), 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: Cross-site Evaluation of the Effectiveness of the Infant Adoption Awareness Training Program (IAATP)—NEW

HRSA proposes to evaluate the Infant Adoption Awareness Training Program being implemented by adoption organizations. The IAATP is authorized under the Children's Health Act of 2000 (CHA), Title XII, Subtitle A to develop, implement and evaluate curricula to achieve the goal of providing adoption information and referrals on an equal basis with other courses of action included in non-directive counseling to pregnant women. National, regional and local organizations whose primary purpose includes adoption were funded under IAATP cooperative agreements to deliver adoption training to health care workers with a special focus on those working in health care facilities funded

under section 1001 and section 330 of the Public Health Service Act and those receiving grants to provide health services in schools. The Children's Health Act mandates that the Secretary submit to Congress a report evaluating the effectiveness of training delivered under the IAATP and the extent to which it results in the provision of adoption information and referrals to pregnant women on an equal basis with other courses of action included in non-directive counseling to pregnant women.

To determine if the IAATP is effective in achieving the intent of the congressional mandate, the proposed study will assess the effect of IAATP training on knowledge, attitudes and self-reported practices for health care workers who counsel pregnant women in health care settings. An estimated 1,752 health care workers who regularly counsel pregnant women and who completed IAATP training will be recruited into the study and will complete a 15 minute mail survey instrument covering the time and extent of their exposure to the IAATP training, as well as knowledge, attitudes and self-reported practices in providing adoption information and referrals to pregnant women. A comparison group of 572 health care workers who perform pregnancy counseling but did not receive the IAATP training, will receive a mail survey on their knowledge, attitudes and self-reported behaviors in providing adoption information and referrals to the pregnant women that they counsel.

In addition, staff of each of the four grantees, their trainers and trainees will participate in interviews and focus groups to document the program development and training processes and delivery of the IAATP. For each grantee, there will be one and half hour individual interviews of grantee staff, one focus group of trainers from each of four grantees, and two focus groups of trainees from each of four grantee programs.

Respondents	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Trainee Survey .....	1,144	1	.25	286
Comparison Group Survey .....	572	1	.25	143
Telephone Focus Group .....	36	1	1.5	54
Total .....	1,752	.....	.....	483

Written comments and recommendations concerning the proposed information collection should

be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management

and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.