person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. FDA uses the information provided in the request to determine whether to grant the petition for reconsideration. Respondents to this collection of information are individuals of households, State or local governments, not-for-profit institutions, and businesses or other for-profit instructions who are requesting from the Commissioner a reconsideration of a matter. Section 10.35 (21 CFR 10.35) issued under section 701(a) of the act, sets forth the format and procedures by which an interested person may request, in accordance with § 10.20 (submission of documents to the Dockets Management Branch), the Commissioner to stay the effective date of any administrative action. Such a petition must: (1) Identify the decision involved, (2) state the action requested including the length of time for which a stay is requested, and (3) include a statement of the factual and legal grounds on which the interested person relies in seeking the stay. FDA uses the information provided in the request to determine whether to grant the petition for stay of action. Respondents to this information collection are interested persons who choose to file a petition for an administrative stay of action. Section 10.85 (21 CFR 10.85), issued under section 701(a) of the act, sets forth the format and procedures by which an interested person may request, in accordance with § 10.20 (submission of documents to the Dockets Management Branch), an advisory opinion from the Commissioner on a matter of general applicability. An advisory opinion represents the formal position of FDA on a matter of general applicability. When making a request, the petitioner must provide a concise statement of the issues and questions on which an opinion is requested, and, a full statement of the facts and legal points relevant to the request. Respondents to this collection of information are interested persons seeking an advisory opinion from the Commissioner on the agency's formal position for matters of general applicability.

In the **Federal Register** of July 9, 2002 (67 FR 45525), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.30	150	3	450	12	5,400
10.33	10	1	10	10	100
10.35	13	1	13	10	130
10.85	3	1	3	16	48
Total					5,678

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates for this collection of information is based on agency records and experience over the past 3 years. Agency personnel handling the petitions for § 10.30 estimate 150 (citizen petitions) received by the agency annually, each requiring an average of 12 hours preparation time. Agency personnel handling the petitions for § 10.33 (administrative reconsideration of an action) estimate 10 requests are received by the agency annually, each requiring an average of 10 hours preparation time. Agency personnel handling the petitions for § 10.35 (administrative stay of an action) estimate 13 requests are received by the agency annually, each requiring an average of 10 hours preparation time. Agency personnel handling the petitions for § 10.85 (advisory opinions) estimate three requests are received by the agency annually, each requiring an average of 16 hours preparation time.

Dated: December 6, 2002.

Margaret M.Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 02–31722 Filed 12–17–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01P–0150]

Salad Dressing Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the extension of a temporary permit issued to Kraft Foods, Inc., to market test products designated as ''salad dressing'' that deviate from the U.S. standard of identity for salad dressing. The extension will allow the permit holder to continue to collect data on the consumer acceptance of products, identify mass production problems, and assess commercial feasibility, in support of a petition to amend the standard of identity for salad dressing.

DATES: The new expiration date of the permit will be either 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 the case may be.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS–822), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION: In accordance with § 130.17 (21 CFR 130.17), FDA issued a temporary permit to Kraft Foods, Inc., Three Lakes Dr., Northfield, IL 60093–2753, to market test products identified as ''salad dressing'' that deviate from the requirement of the standard of identity for salad dressing in 21 CFR 169.150 (66 FR 18957, April 12, 2001). The agency issued the permit to facilitate market testing of products that deviate from the requirements of the standard of identity for salad dressing issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). The permit covers limited interstate market testing of products that deviate from the standard for salad dressing in 21 CFR 169.150. The products may contain potassium sorbate at levels not to exceed 1 percent, and must contain not less yolk-containing ingredient than is equivalent to 2 percent by weight of liquid egg yolks (the food standard

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, which 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.

[FR Doc. 02–31720 Filed 12–17–02; 8:45 am]

BILLING CODE 4160–01–S

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/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