DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1220]

Human Food By-Products for Use as Animal Food; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GIF) #239 entitled ''Human Food By-Products For Use As Animal Food.'' This draft guidance helps domestic and foreign facilities that are required to register as food facilities under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), because they manufacture, process, pack, or hold human food for consumption in the United States, determine what requirements to follow for their human food by-products for use as animal food and provides examples and recommendations for how to meet those requirements.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 23, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–1220 for ''Human Food By-Products for Use as Animal Food; Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Policy and Regulations Staff (HFV–6), 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.

FOR FURTHER INFORMATION CONTACT: Jeanette Murphy, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6246, *jenny.murphy@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft GIF #239 entitled ''Human Food By-Products for Use as Animal Food.'' This draft guidance is intended for domestic and foreign facilities that are required to register as food facilities under the FD&C Act because they manufacture, process, pack, or hold human food for consumption in the United States, which results in by-products for use as animal food.

This draft guidance contains information for these facilities to determine what requirements to follow for their human food by-products for use as animal food and provides examples and recommendations for how they might meet those requirements. The requirements were established in the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals final rule published on September 17, 2015 (80 FR 56170). The requirements are codified in 21 CFR parts 117 and 507.

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 current

thinking of FDA on human food by-products for use as animal food. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 507 have been approved under OMB control number 0910–0789.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: August 19, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2016–20302 Filed 8–24–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Study To Estimate Radiation Doses and Cancer Risks From Radioactive Fallout From the Trinity Nuclear Test—National Cancer Institute (NCI)

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Cancer Institute, the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 13, 2016, p 29875 and allowed 60-days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Steven L. Simon, Dosimetry Unit Head and Staff Scientist, Radiation Epidemiology Branch, Division of Cancer Epidemiology & Genetics, National cancer Institute, NIH, 9609 Medical Center Drive, MSC9778, Bethesda, MD 20892–9778 or call non-toll-free number (240)-276–7371 or email your request, including your address to: *ssimon@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The National Cancer Institute, NCI, National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Study to Estimate Radiation Doses and Cancer Risks from Radioactive Fallout from the Trinity Nuclear Test, 0925–NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This Information Collection Request is for a radiation-related cancer risk projection study for the residents of the state of New Mexico (NM) potentially exposed to radioactive fallout from the Trinity nuclear test conducted in 1945. Data will be collected on diet and lifestyle from three groups in NM (non-Hispanic white, Hispanic, and Native American) alive in the 1940s via focus groups and key informant interviews. These data will be used to derive means and ranges of exposure-related parameters. Little information is currently available about dietary patterns among Native American community members or Hispanics in New Mexico in the 1940s. Exposure-related parameter values will be used with historical fallout deposition data in fallout dose assessment models to estimate external and internal radiation doses to representative persons in all counties in New Mexico by ethnicity and age. The estimated doses will be used with literature-derived risk and parameter values on risk/unit dose to project the excess cancers expected (per 1,000 persons within each stratum) including uncertainty on each estimate. Endpoints are leukemia, thyroid cancer, stomach cancer, colon cancer, and all solid cancers combined.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 536.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Instrument	Number of respondents	Frequency of response	Average time per response (in hours)	Annual burden hours
Individuals	Screener	315	1	10/60	53
	Consent Form	210	1	10/60	35
	Focus Groups	168	1	120/60	336
	Pre-Focus Group Guide	168	1	10/60	28
	Key Informant and Academic Interview.	42	1	120/60	84
Totals		210	525		536