

Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition” identifies, interprets, and clarifies existing requirements imposed by statute and regulation, consistent with the Council on Environmental Quality regulations (40 CFR 1507.3). It consists of recommendations that do not themselves create requirements; rather, they are explanatory guidance for FDA’s own procedures in order to ensure full compliance with the purposes and provisions of NEPA.

The guidance provides information to assist in the preparation of claims of categorical exclusion and EAs for

submission to CFSAN. The following questions are covered in this guidance: (1) What types of industry-initiated actions are subject to a claim of categorical exclusion? (2) What must a claim of categorical exclusion include by regulation? (3) What is an EA? (4) When is an EA required by regulation and what format should be used? (5) What are extraordinary circumstances? and (6) What suggestions does CFSAN have for preparing an EA? Although CFSAN encourages industry to use the EA formats described in the guidance because standardized documentation submitted by industry increases the efficiency of the review process, alternative approaches may be used if

these approaches satisfy the requirements of the applicable statutes and regulations.

FDA is requesting the extension of OMB approval for the information collection provisions in the guidance.

Description of Respondents: The likely respondents include businesses engaged in the manufacture or sale of food, food ingredients, and substances used in materials that come into contact with food.

In the **Federal Register** of March 28, 2007 (72 FR 14581), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.32(i)	52	3	156	1	156
25.32(o)	1	1	1	1	1
25.32(q)	7	2	14	1	14
Total			171		171

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

The estimates in table 1 of this document for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for § 25.32(i) and (q) that the agency has received in the past 3 years. Please note that, in the past 3 years, there have been no submissions that requested an action that would have been subject to the categorical exclusion in § 25.32(o). To avoid counting this burden as zero, FDA has estimated the burden for this categorical exclusion at one respondent making one submission a year for a total of one annual submission.

To calculate the estimate for the hours per response values, we assumed that the information requested in this guidance for each of these three categorical exclusions is readily available to the submitter. For the information requested for the exclusion in § 25.32(i), we expect that submitter will need to gather information from appropriate persons in the submitter’s company and to prepare this information for attachment to the claim for categorical exclusion. We believe that this effort should take no longer than 1 hour per submission. For the information requested for the exclusions in § 25.32(o) and (q), the submitters will almost always merely need to copy existing documentation and attach it to the claim for categorical exclusion. We

believe that collecting this information should also take no longer than 1 hour per submission.

Dated: June 14, 2007.
Jeffrey Shuren,
Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0230]

Agency Information Collection Activities; Proposed Collection; Comment Request; Information From United States Processors That Export to the European Community

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed

extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements in implementing the lists of U.S. firms/processors exporting shell eggs, dairy products, game meat and game meat products to the European Community (the EC).

DATES: Submit written or electronic comments on the collection of information by August 20, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of

information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the

information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Information From U.S. Processors That Export to the European Community (OMB Control Number 0910-0320)—Extension

The EC is a group of 27 European countries that have agreed to harmonize their commodity requirements to facilitate commerce among member States. EC legislation for intra-EC trade has been extended to trade with non-EC countries, including the United States. For certain food products, including those listed in this document, EC legislation requires assurances from the responsible authority of the country of origin that the processor of the food is in compliance with applicable regulatory requirements.

FDA requests information from processors that export certain animal-derived products (e.g., shell eggs, dairy products, game meat, game meat products, animal casings, and gelatin) to the EC. FDA uses the information to

maintain lists of processors that have demonstrated current compliance with U.S. requirements and provides the lists to the EC quarterly. Inclusion on the list is voluntary. EC member countries refer to the lists at ports of entry to verify that products offered for importation to the EC from the United States are from processors that meet U.S. regulatory requirements. Products processed by firms not on the lists are subject to detention and possible refusal at the port. FDA requests the following information from each processor seeking to be included on the lists:

1. Business name and address;
2. Name and telephone number of person designated as business contact;
3. Lists of products presently being shipped to the EC and those intended to be shipped in the next 6 months;
4. Name and address of manufacturing plants for each product; and
5. Names and affiliations of any Federal, State, or local governmental agencies that inspect the plant, government-assigned plant identifier such as plant number, and last date of inspection.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Products	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Shell Eggs	10	1	10	0.25	3
Dairy	120	1	120	0.25	30
Game Meat and Meat Products	5	1	5	0.25	1
Animal Casings	5	1	5	0.25	1
Gelatin	3	1	3	0.25	1
Collagen	3	1	3	0.25	1
Total					37

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

FDA bases its estimate on the responses received over the past 3 years. We estimate that the annual reporting burden would be approximately 37 hours. The time to respond to the questions should take approximately 15 minutes using any of the technologies available to transmit the information. All of the information asked for should be readily available. No record retention is required. In previous years, FDA estimated that the agency's communication with trade associations and states resulted in a reporting burden of 520 hours. FDA no longer receives

information from trade associations and states under this program. Accordingly, the proposed annual burden for this information collection has been reduced by 520 hours. Therefore, the proposed annual burden for this information collection is 37 hours.

Dated: June 14, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0227]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices Third-Party Review Under the Food and Drug Administration Modernization Act

AGENCY: Food and Drug Administration, HHS.