Respondents	No. of respondents	No. of respondents/response	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Introductory phone call	140	1	0.10	14
Baseline questionnaire	140	1	0.75	105
Self-reported daily diary	140	42	0.25	1470
Total				1589

Dated: December 11, 1996.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–32063 Filed 12–17–96; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 96N–0373]

Agency Information Collection Activities: Proposed Collection; Reinstatement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on proposed collections of certain information by the agency. Under the Paperwork Reduction Act of 1995, Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the maintenance of lists of U.S. processors that export certain animal-derived foods (i.e., shell eggs, dairy products, game meat, and game meat products) to the European Community (EC), temporary exemptions from certain food labeling requirements for the purpose of conducting authorized food labeling experiments, petitions for health claims, and petitions for nutrient content claims.

DATES: Submit written comments on the collections of information by February 18, 1997.

ADDRESSES: Submit written comments on the collections of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kimberly A. Sanders, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1473.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 or reinstatement 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 collections of information listed below.

With respect to each of the following collections of information, FDA invites comments on: (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.

1. Request for Information From U.S. Processors that Export to the European Community (OMB Control Number 0910–0320—Reinstatement)

EC is a group of 15 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 below, 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.

With the assistance of trade associations and State authorities, FDA intends to request information from processors that export certain animal-derived products (shell eggs, dairy products, game meat, and game meat products) to EC. FDA will use the information to maintain lists of processors that have demonstrated current compliance with U.S. requirements and will provide the lists to EC quarterly. Inclusion on the list is voluntary. EC member countries will refer to the lists at ports of entry to verify that products offered for importation to EC from the United States are from processors that meet U.S. regulatory requirements. Products processed by firms not on the processor list are subject to detention and possible refusal at the port. FDA intends to request the following information from each processor:

(1) Business name and address;

(2) Name and telephone number of person designated as business contact;

(3) Lists of products presently being shipped to EC and those intended to be shipped in the next 6 months;

(4) Name and address of manufacturing plants for each product;

(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; and

(6) Assurance that the firm or individual representing the firm and

submitting a certificate for signature to FDA is aware of and knows that they are subject to the provisions of Section 1001 of Title 18, United States Code. This law provides that it is a criminal offense to knowingly and willfully make a false statement or alter or counterfeit documents in a matter within the jurisdiction of a U.S. agency.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

Products	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Shell Eggs	50	1	50	0.25	12.50
Dairy	250	1	250	0.25	62.50
Game Meat and Game Meat Products	75	1	75	0.25	18.75
Total	375	1	375	0.25	93.75

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

The burden estimate is based on the time needed to write and transmit information which is readily available to the respondents. The number of respondents is based on prior responses to a request for this information.

Third Party Disclosure

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN

Respondent	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating and Maintenance Costs
Trade Association	14	1	14	8	112	$7,000
State	50	1	50	8	400	$2,500

There are no capital costs associated with this collection.

The burden estimated for the trade associations assumes the trade associations will disseminate FDA's information request through mass mailings to their membership or publish it in their trade magazine or newsletter. The burden estimated for State authorities assumes dissemination of information to the processors or dissemination of information about the processors to FDA.

2. Exemptions Petitions for the Conduct of Food Labeling Experiments—21 CFR 101.108 (OMB Control No. 0910–0151—Reinstatement)

Under the authority of section 403(q) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(q)), FDA issued requirements for the declaration of nutrition information on food labels and labeling, including § 101.9 (21 CFR 101.9). Section 101.9 prescribes the format, including graphics and style, as well as alternative approaches, that are to be used by food producers in presenting nutrition information on the labels and labeling of their food products. FDA provides authorization in § 101.108 (21 CFR 101.108), in the form of temporary exemptions, for food producers to experiment with graphics and other formats for presenting nutrition and other related food labeling information. The information required under § 101.108(b) is needed to monitor the labeling of experimental packs of food deviating from the requirements of nutrition labeling. The information obtained in these experiments can be used in support of petitions to amend the nutrition labeling regulations to provide for the variations. The respondents for this collection are businesses or other for-profit organizations.

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

TABLE 3.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
101.108	0	1	0	40	0

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

The reporting burden for § 101.108 is insignificant because exemption petitions are seldom submitted for the conduct of food labeling experiments. Over the last 3 years, FDA has not received any exemption petitions. Since the regulation was originally adopted on April 8, 1983, FDA has received only a few requests for temporary exemptions for the purposes of conducting authorized food labeling experiments.

3. Petitions for Health Claims—21 CFR 101.70(f) (OMB Control No. 0910–0287—Reinstatement)

Section 403(r)(4) of the act provides for the submission of petitions to FDA requesting the issuance of a regulation authorizing a health claim on a substance-disease relationship. Section

101.70(f) (21 CFR 101.70(f)) sets forth the information a person is required to supply in such a petition. This information will be used by the agency in determining whether a petition meets the requirements for issuing a regulation authorizing a health claim, thereby ensuring that the public health is protected. The respondents for this collection are businesses, other for-profit organizations, or not-for-profit organizations.

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

TABLE 4.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating and Maintenance Costs
101.70(f)	3	1	3	80	240	?	?

Where question marks (?) appear, FDA has no information on which to determine whether there are capital costs or operating and maintenance costs associated with this collection. FDA is asking for comments on the extent to which there are capital costs or operating and maintenance costs associated with this collection.

FDA has estimated the average costs and burdens above based on its experience with health claim petitions that have been submitted to the agency. In the more than 3 years since § 101.70(f) became effective, FDA has received less than 10 health claims petitions. The hour burden is based on FDA's estimate of the average amount of time required to prepare these petitions.

4. Petitions for Nutrient Content Claims—21 CFR 101.69(m), (n), and (o) (OMB Control No. 0910–0288—Reinstatement)

Section 403(r)(4) of the act provides for the submission of petitions to FDA requesting the issuance of regulations authorizing a nutrient content claim characterizing the amount of a nutrient in a food product. Section 101.69(m)(1), (n)(1), and (o)(1) (21 CFR 101.69(m)(1), (n)(1), and (o)(1)) sets forth data requirements specific for nutrient content claims petitions, synonym petitions, and brand-name petitions, respectively. This information is used by FDA in determining whether a petition meets the requirements of the regulations for the issuance of a regulation providing for a nutrient content claim. The respondents for this collection are businesses, other for-profit organizations, or not-for-profit organizations.

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

TABLE 5.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating and Maintenance Costs
101.69(m)(1)	1	1	1	40	40	?	?
101.69(n)(1)	1	1	1	20	20	?	?
101.69(o)(1)	1	1	1	20	20	?	?
Totals					80	?	?

Where question marks (?) appear, FDA has no information on which to determine whether there are capital costs or operating and maintenance costs associated with this collection. FDA is asking for comments on the extent to which there are capital costs or operating and maintenance costs associated with this collection.

FDA has estimated the average costs and burdens above based on its experience with nutrient content claim petitions that have been submitted to the agency. In the more than 2 years since § 101.69(m), (n), and (o) became effective, FDA has received only one nutrient content claim petition under § 101.69(n). The hour burden is based on FDA's estimate of the average amount of time required to prepare that petition. The hour burden for § 101.69(m) and (o) is based on the assumption that one petition would be submitted under each provision and that the information requirements are more complex (§ 101.69(m)) or about the same (§ 101.69(o)) as for § 101.69(n)).

Dated: December 11, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32034 Filed 12–17–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0393]

Agency Information Collection Activities: Proposed Collection; Comment Request; Reinstatement

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, Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on MEDWATCH medical product reporting program forms, FDA form 3500 and 3500A.

DATES: Submit written comments on the collection of information by February 18, 1997.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.