administrative aspects of acquisition-supported activities to assure compliance with appropriate DHHS and CDC policies and application to public health activities; (4) gives technical assistance, where indicated, to improve the management of acquisition activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC program offices and the public; (5) performs contract and purchasing administrative activities including coordination and negotiation of contract modifications, reviewing and approving contractor billings, resolving audit findings, and performing close-out/termination activities; (6) provides for the collection and reporting of business management and public health programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; (7) assures that contractor performance is in accordance with contractual commitments; (8) provides leadership and guidance to CDC project officers and program officials; (9) provides leadership, direction, procurement options, and approaches in developing specifications/statements of work and contract awards; (10) participates with top program management in public health program planning, policy determination, evaluation, and directions concerning acquisition strategies and execution; (11) maintains branch's official contract files; (12) maintains a close working relationship with CDC program office components in carrying out their missions; and (13) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO and CDC.

Logistics Management Branch (CAJHW). (1) Develops and implements CDC-wide policies, procedures, and criteria necessary to comply with federal and departmental regulations governing personal property, transportation, shipping, and fleet management; (2) determines, recommends, and implements procedural changes needed to maintain effective management of CDC property including but not limited to: Inventory control; property records; receipt, delivery, tracking, shipping and return of CDC materiel; property reutilization and disposal; transportation of freight; and CDC's vehicle fleet; (3) provides audits, training and technical assistance to CDC Centers/Institute/Offices on property, transportation, shipping, and fleet management; (4) determines the requirement for and serves as the functional proponent for the design, test, and implementation of logistics management systems; (5) represents CDC on inter-and intra-departmental committees relevant to logistical functions; (6) serves as the CDC liaison to HHS and other federal agencies on logistical matters such as property, transportation and traffic management; and (7) establishes branch goals, objectives and priorities, and assures consistency and coordination with overall Procurement and Grants Office logistical goals and objectives.

Dated: July 3, 2012.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2012–17990 Filed 7–25–12; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0454]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 27, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0640. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act—(OMB Control Number 0910–0640)—Extension

On December 22, 2006, the President signed into law the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109–462, 120 Stat. 3469). This law amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) with respect to serious adverse event reporting for dietary supplements and nonprescription drugs marketed without an approved application.

Section 502(x) of the FD&C Act (21 U.S.C. 352(x)), which was added by Public Law 109–462, requires the label of a nonprescription drug product marketed without an approved application in the United States to include a domestic address or domestic telephone number through which a responsible person may receive a report of a serious adverse event associated with the product. The guidance document contains questions and answers relating to this labeling requirement and provides guidance to industry on the following topics: (1) The meaning of ''domestic address'' for purposes of the labeling requirements of section 502(x) of the FD&C Act; (2) FDA's recommendation for the use of an introductory statement before the domestic address or phone number that is required to appear on the product label under section 502(x) of the FD&C Act; and (3) FDA's intent regarding enforcing the labeling requirements of section 502(x) of the FD&C Act. Separate guidance, issued by the Center for Food Safety and Applied Nutrition on reporting for dietary supplements, is announced elsewhere in the **Federal Register**.

Title: Guidance for Industry on Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.

Description of Respondents: Respondents to this collection of information are manufacturers, packers, and distributors whose name (under section 502(b)(1) of the FD&C Act) appears on the label of a nonprescription drug product marketed in the United States without an approved application.

Burden Estimate: FDA is requesting public comment on the estimated one-time reporting burden from these respondents, as required by 502(x) of the FD&C Act and described in the guidance ''Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' The estimates for one-time reporting are based on FDA's knowledge of nonprescription drug product labeling in the United States, whether or not marketed under an approved application.

In the **Federal Register** of May 15, 2012 (77 FR 28604), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on the information collection.

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

TABLE 1—ESTIMATED ONE-TIME REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total responses	Average burden per response	Total hours
Domestic address or phone number labeling requirement (21 U.S.C. 502(x)) and recommendation to clarify its purpose	200	500	100,000	4	400,000

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

As indicated in table 1 of this document, FDA estimates that approximately 200 manufacturers will revise approximately 100,000 labels to add a full domestic address and a domestic telephone number, and should they choose to adopt the guidance's recommendation, to add a statement identifying the purpose of the domestic address or telephone number. FDA believes that designing the label change should not take longer than 4 hours per label. Automated printing of the labels should only require a few seconds per label. This estimate accounts for the possibility that every manufacturer will make label revision, which is unlikely. Because the majority of over-the-counter drug product labels currently have a domestic telephone number that satisfies the requirement, we believe many manufacturers will opt not to adopt the guidance's recommendation to add a statement identifying the purpose of the address or telephone number, significantly reducing the number of total responses. However, assuming that all labels are revised, we estimate a one-time reporting burden for this information collection of 400,000 hours.

Dated: July 18, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–18233 Filed 7–25–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0473]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 27, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to o*ira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0186. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, 301–796–5733, *domini.bean@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Irradiation in the Production, Processing, and Handling of Food—21 CFR Part 179 (OMB Control Number 0910–0186)—Extension

Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(s) and 348), food irradiation is subject to regulation under the food additive premarket approval provisions of the FD&C Act. The regulations providing for uses of irradiation in the production, processing, and handling of food are found in part 179 (21 CFR part 179). To ensure safe use of a radiation source, § 179.21(b)(1) requires that the label of sources bear appropriate and accurate information identifying the source of radiation and the maximum (or minimum and maximum) energy of radiation emitted by X-ray tube sources. Section 179.21(b)(2) requires that the label or accompanying labeling bear adequate directions for installation and use and a statement supplied by FDA that indicates maximum dose of radiation allowed. Section 179.26(c) requires that the label or accompanying labeling bear a logo and a radiation disclosure statement. Section 179.25(e) requires that food processors who treat food with radiation make and retain, for 1 year past the expected shelf life of the products up to a maximum of 3 years, specified records relating to the