Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *grjohnson@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: March 23, 2005

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 05–6170 Filed 3–28–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0554]

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 April 28, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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 179.21 (OMB Control Number 0910–0549)—Extension

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless it conforms to the terms of a regulation prescribing its use, or to an exemption for investigational use, or in the case of a food additive that is a food contact substance, there is in effect a regulation prescribing the conditions under which such additive may be safely used or a notification that is effective. In response to a petition that is submitted under section 409 of the act to establish that a food additive is safe, the agency may either: (1) By order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or (2) by order deny the petition and notify the petitioner of such order and of the reasons for such action.

In response to a petition filed by Science Applications International Corp., who subsequently transferred their rights to the petition to Ancore Corp., FDA published in the **Federal Register** of December 21, 2004, a document that amended 21 CFR 179.21 to provide for the use of sources of monoenergetic neutrons to inspect cargo containers that may contain food. Under this regulation, monoenergetic neutron sources producing neutrons at energies not less than 1 million electron volts (MeV) but no greater than 14 MeV may be used for inspection of cargo containers that may contain food, providing that the neutron source bears a label stating the minimum and maximum energy of radiation emitted by the source. The regulation also requires that the label or accompanying labeling bear adequate directions for safe use and a statement that no food shall be exposed to this radiation source so as to receive a dose in excess of 0.01 gray. FDA has determined that this information is needed to assure safe use of the source of radiation.

In the **Federal Register** of January 4, 2005 (70 FR 366), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Number of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours Per Response	Total Operating and aintenance Costs	Total Hours
179.21(a)(5) and (b)(2)(v)	1	1	1	1	$100	1

[1]There are no capital costs associated with this collection of information.

FDA estimates that the burden will be insignificant because the reporting requirement reflects customary business practice. Based on discussions with an industry representative, the burden hours estimated for this collection of information is 1 hour. The operating and maintenance cost associated with this collection is $100 for preparation of labels.

Dated: March 21, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–6086 Filed 3–28–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0534]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Format and Content for Over-the-Counter Drug Product Labeling

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 (the PRA).

DATES: Fax written comments on the collection of information by April 28, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Format and Content for Over-the-Counter (OTC) Drug Product Labeling—(OMB Control Number 0910–0340)—Extension

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA amended its regulations governing requirements for human drug products to establish a standardized format for the labeling of all over-the-counter (OTC) drug products. The rule added new § 201.66 (21 CFR 201.66) and requires OTC drug product labeling to include uniform headings and subheadings, presented in a standardize order, with minimum standards for type size and other graphic features. The rule is intended to enable consumers to better read and understand OTC drug product labeling and to apply this information to the safe and effective use of OTC drug products. FDA concludes that the labeling statements required under this rule are not subject to review by the OMB because they are ''a public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and therefore do not constitute a ''collection of information'' under the PRA (44 U.S.C. 3501 *et seq.*).

Section 201.66 of the labeling requirements requires all OTC drug manufacturers to format labeling as set forth in paragraphs (c) and (d). FDA has learned from the industry that OTC drug product manufacturers routinely redesign the labeling of their products as part of their usual and customary business practice. The rule provides varied timeframes for implementing the OTC labeling requirements. Therefore, the majority of respondents have been able to format OTC drug product labeling in accordance with § 201.66 as part of their routine redesign practice, creating no additional paperwork or economic burden.

In discussing the collection of information under the PRA in the final rule (64 FR 13254 at 13274 to 13276), FDA estimated that, of the 39,310 stock keeping units (SKUs) (individual products, packages, and sizes) marketed under a final monograph when the OTC labeling requirements were issued on March 17, 1999, approximately 32 percent, or 12,573 products, may necessitate labeling format changes sooner than provided under their usual and customary practice of label design. FDA estimated that of the 400 respondents who produce OTC drug products, including the 12,573 products described above, each may be required to respond approximately 31.4 times to this rule outside of their usual and customary practice. Each response was estimated to take, on the average, 4 hours, for a total of 50,292 hours per year. This burden was expected to be a one-time burden.

FDA stated that although the usual and customary practice of label redesign would minimize the burden for the remaining 68 percent of SKUs, or 26,737 products, marketed at the time the OTC labeling requirements were issued on March 17, 1999, additional time may be necessary for each company to make the format changes under this rule. FDA estimated that of the 400 respondents who produce OTC drug products, each may be required to respond approximately 66.8 times to bring the 26,737 products into compliance with the rule. FDA estimated that for this group, each response will take an average of 2.5 hours for a total of 66,842 hours. This burden was expected to be a one-time burden.

Finally, FDA estimated that approximately 61 respondents hold new drug applications (NDAs) and abbreviated new drug applications (ANDAs) (41 NDA holders and 20 ANDA holders) for which supplements and amendments would be required. FDA expected that 522 submissions (350 to NDAs and 172 to ANDAs) would be required for labeling changes under § 201.66(c) and (d), which averages to 8.5 submissions per respondent. FDA estimated that each submission wouldtake an average of 2 hours to prepare for a total of 1,040 hours annually. This burden was also expected to be a one-time burden.

Since the final rule was issued on March 17, 1999, FDA extended the May 16, 2001, compliance date by 1 year to May 16, 2002 (with a corresponding extension of the May 16, 2002, compliance date for products with annual sales of less than $25,000 to May 16, 2003) (65 FR 38191, June 20, 2000). Since March 17, 1999, FDA has published 6 additional major final rules on OTC drug monographs and several minor amendments to existing final monographs. The effective date for relabeling the OTC drug products affected by these final monographs in the new format occurred by the end of 2004, except for OTC sunscreen drug products (for which implementation of the new labeling requirements has been stayed indefinitely while FDA amends the monograph for these products) and a small number of other OTC drug products with annual sales less than $25,000. Based on information in the 6 final rules issued since 1999, FDA estimates that 11,250 additional SKUs (out of the original 26,737 that needed to be relabeled in the new format) have