2002, or by May 16, 2005, whichever occurs first.

Since March 17, 1999, FDA has published six major final rules on OTC drug monographs and several minor amendments to existing final monographs. The following are the six major final rules and their date of publication:

- Sunscreen drug products (May 21, 1999),
- Cough-cold combination drug products (December 23, 2002),
- Antidiarrheal drug products (April 17, 2003),
- Ingrown toenail relief drug products (May 7, 2003),
- Skin protectant drug products (June 4, 2003), and
- Antiperspirant drug products (June 9, 2003).

The effective date for the final monograph for OTC sunscreen drug products and for the implementation of the new labeling format for these products has been stayed indefinitely (65 FR 36319, June 8, 2000, and 69 FR 53801, September 3, 2004). The effective date for products subject to the final rules on the other OTC drug monographs to implement the new labeling format will occur by the end of 2004, except for a small number of products with annual sales less than $25,000. Those products will have until June 2005 to implement the new labeling format. These dates should enable manufacturers to coordinate the relabeling required by the final monographs with the relabeling required by the OTC drug product labeling final rule.

FDA previously estimated that 12,573 out of 39,310 SKUs were affected by the March 17, 1999, OTC drug product labeling final rule. Based on information in the six final rules issued since that time, FDA estimates that 11,250 additional SKUs have already been affected by the OTC drug product labeling final rule. Thus, 15,487 SKUs remain to be affected by the OTC drug product labeling final rule. All of these will need to implement the new labeling format by May 16, 2005, except for the sunscreen drug products that are currently deferred.

As the number of products remaining to be affected by the OTC drug product labeling final rule is close to the number of products affected at the time of the May 17, 1999, publication of that final rule, FDA is listing the same numbers of respondents, annual frequency per response, and total annual responses in this notice.

FDA believes the hours per response and total hours may be less than the numbers stated in the final rule for several reasons. First, respondents have made a number of inquiries to FDA already since the final rule was issued in 1999. FDA's experience with these inquiries is that inquiries have been less than 2.5 or 4 hours per response, generally averaging 0.25 to 0.5 hour per inquiry. Second, respondents have gained significant experience with the final rule since 1999, reducing their need to make additional inquiries. Third, FDA issued a draft guidance for industry entitled ''Labeling Over-the-Counter Human Drug Products; Updating Labeling in ANDA's'' (66 FR 11174, February 22, 2001), which included a number of labeling examples to assist holders of ANDAs for OTC drug products and manufacturers of reference listed drugs (RLDs) for the ANDAs to implement the new OTC drug product labeling regulation. FDA issued a final guidance for industry on October 18, 2002 (67 FR 64402). This guidance should have reduced some of the hours per response and total hours for some NDA and ANDA holders. However, FDA is not currently able to estimate how much time has been reduced. Accordingly, FDA is listing the same hours per response and total hours in this notice as appeared in the March 17, 1999, final rule.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
201.66[2]	400	31.43	12,573	4	50,292
201.66	400	66.8	26,737	2.5	66,842
201.66(c) and (d)[2]	61	8.5	522	2	1,044
201.66(e)	25	4	100	24	2,400
Total					120,578

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]One-time burden.

Dated: December 28, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–27 Filed 1–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0296]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Good Laboratory Practice Regulations for Nonclinical Studies

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 February 3, 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: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 4B–41, Rockville, MD 20857, 301–827–1472.

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.

Good Laboratory Practice (GLP) Regulations for Nonclinical Studies—21 CFR Part 58 (OMB Control Number 0910–0119)—Extension

Sections 409, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348, 355, 360b, 360e) and related statues require manufacturers of food additives, human drugs and biological products, animal drugs, and medical devices to demonstrate the safety and utility of their product by submitting applications to FDA for research or marketing permits. Such applications contain, among other important items, full reports of all studies done to demonstrate product safety in man and/or other animals. In order to ensure adequate quality control for these studies and to provide an adequate degree of consumer protection, the agency issued the GLP regulations. The regulations specify minimum standards for the proper conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures (SOPs), test and control articles, quality assurance, protocol and conduct of a safety study, records and reports, and laboratory disqualification.

The GLP regulations contain requirements for the reporting of the results of quality assurance unit inspections, test and control article characterization, testing of mixtures of test and control articles with carriers, and an overall interpretation of nonclinical laboratory studies. The GLP regulations also contain recordkeeping requirements relating to the conduct of safety studies. Such records include: (1) Personnel job descriptions and summaries of training and experience; (2) master schedules, protocols and amendments thereto, inspection reports, and SOPs; (3) equipment inspection, maintenance, calibration, and testing records; (4) documentation of feed and water analyses and animal treatments; (5) test article accountability records; and (6) study documentation and raw data.

The information collected under GLP regulations is generally gathered by testing facilities routinely engaged in conducting toxicological studies and is used as part of an application for a research or marketing permit that is voluntarily submitted to FDA by persons desiring to market new products. The facilities that collect this information are typically operated by large entities, e.g., contract laboratories, sponsors of FDA-regulated products, universities, or government agencies. Failure to include the information in a filing to FDA would mean that agency scientific experts could not make a valid determination of product safety. FDA receives, reviews, and approves hundreds of new product applications each year based on information received. The recordkeeping requirements are necessary to document the proper conduct of a safety study, to assure the quality and integrity of the resulting final report, and to provide adequate proof of the safety of regulated products. FDA conducts onsite audits of records and reports, during the agency's inspections of testing laboratories, to verify reliability of results submitted in applications.

The likely respondents collecting this information are contract laboratories, sponsors of FDA-regulated products, universities, or government agencies.

In the **Federal Register** of July 22, 2004 (69 FR 43853), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
58.35(b)(7)	300	60.25	18,075	1	18,075
58.185	300	60.25	18,075	27.65	499,774
Total					517,849

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
58.29(b)	300	20	6,000	.21	1,260
58.35(b)(1) through (b)(6) and (c)	300	270.76	81,228	3.36	279,926
58.63(b) and (c)	300	60	18,000	.09	1,620
58.81(a), (b), and (c)	300	301.8	90,540	.14	12,676
58.90(c) and (g)	300	62.7	18,810	.13	2,445
58.105(a) and (b)	300	5	1,500	11.8	17,700
58.107(d)	300	1	300	4.25	1,275
58.113(a)	300	15.33	4,599	6.8	31,273

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
58.120	300	15.38	4,614	32.7	150,878
58.195	300	251.5	75,450	3.9	294,255
Total					793,308

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

Dated: December 28, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–28 Filed 1–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0554]

Agency Information Collection Activities; Proposed Collection; Comment Request; 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 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 the collection of information from manufacturers of monoenergetic neutron sources in order to comply with an amendment to FDA's food additive regulations.

DATES: Submit written or electronic comments on the collection of information by March 7, 2005.

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

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.

Irradiation in the Production, Processing, and Handling of Food—21 CFR 179.21 (OMB Control Number 0910–0549)—Extension

In the **Federal Register** of December 21, 2004 (69 FR 76401), FDA announced OMB's approval of this collection of information (OMB control number 0910–0549). Since this was an emergency approval that expires on January 31, 2005, FDA is following the normal PRA clearance procedures by issuing this document.

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