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

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record-keeper	Total Hours
211.122(c)	4,184	50	209,200	.25	52,300
211.130(e)	4,184	50	209,200	.25	52,300
211.132(c)	1,698	20	33,960	.5	16,980
211.132(d)	1,698	.2	340	.5	170
211.137	4,184	5	20,920	.5	10,460
211.160(a)	4,184	2	8,368	1	8,368
211.165(e)	4,184	1	4,184	1	4,184
211.166(c)	4,184	2	8,368	.5	4,184
211.173	1,077	1	1,077	.25	269
211.180(e)	4,184	.2	837	.25	209
211.180(f)	4,184	.2	837	1	837
211.182	4,184	2	8,368	.25	2,092
211.184	4,184	3	12,552	.5	6,276
211.186	4,184	10	41,840	2	83,680
211.188	4,184	25	104,600	2	209,200
211.192	4,184	2	8,368	1	8,368
211.194	4,184	25	104,600	.5	52,300
211.196	4,184	25	104,600	.25	26,150
211.198	4,184	5	20,920	1	20,920
211.204	4,184	10	41,840	.5	20,920
Total					848,625

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

Dated: January 31, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–3023 Filed 2–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0459]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit written comments on the collection of information by March 11, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (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.

Food Labeling; Notification Procedures for Statements on Dietary Supplements—21 CFR Part 101.93 (OMB Control No. 0910–0331)—Extension

Description: Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(6)) requires that the agency be notified by manufacturers, packers, and distributors of dietary supplements that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the act. Section 403(r)(6) of the act requires that the agency be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) a signature of a responsible individual who can certify the accuracy of the information presented.

The agency established § 101.93 (21 CFR 101.93) as the procedural regulation for this program. Section 101.93 provides details of the procedures associated with the submission and identifies the information that must be included in order to meet the requirements of section 403 of the act.

Description of Respondents: Businesses or other for-profit organizations.

In the **Federal Register** of October 25, 2001 (66 FR 54017), the agency requested comments on the proposed collection of information. Several comments were received that were not the subject of this information collection.

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
101.93	2,500	1	2,500	.75	1,875

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

The agency believes that there will be minimal burden on the industry to generate information to meet the requirements of section 403 of the act in submitting information regarding section 403(r)(6) of the act statements on labels or labeling of dietary supplements. The agency is requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its labeling or in its labeling. This estimate is based on the average number of notification submissions received by the agency in the preceding 18 months.

Dated: January 31, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–3022 Filed 2–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0785]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Revised Draft Guidance for Industry on Developing Medical Imaging Drugs and Biologics

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit written comments on the collection of information by March 11, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (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.

Revised Draft Guidance for Industry on Developing Medical Imaging Drugs and Biologics

In the **Federal Register** of October 14, 1998 (63 FR 55067), FDA published a notice announcing the availability of a draft guidance for industry entitled ''Developing Medical Imaging Drugs and Biological Products.'' In response to comments and on its own initiative, FDA made several revisions to the draft guidance. The agency announced the availability of a revised draft guidance in the **Federal Register** of July 31, 2000 (65 FR 46674).

The draft guidance is intended to assist developers of drug and biological products used for medical imaging in planning and coordinating the clinical investigations of and submitting various types of applications for, such products.

The draft guidance also provides information on how the agency will interpret and apply provisions in the final rule, published in the **Federal Register** of May 17, 1999 (64 FR 26657), on the evaluation and approval of in vivo radiopharmaceuticals used in the diagnosis and monitoring of diseases. The final rule describes certain types of indications for which FDA will approve diagnostic radiopharmaceuticals and lists factors that the agency will consider in evaluating the safety and effectiveness of a diagnostic radiopharmaceutical drug or biological product under the Federal Food, Drug, and Cosmetic Act (the act) or the Public Health Service Act (the PHS Act), respectively.

The draft guidance applies to medical imaging agents that are used for diagnosis and monitoring and that are administered in vivo. Such agents include contrast agents used with medical imaging techniques such as radiography, computed tomography, ultrasonography, and magnetic resonance imaging, as well as radiopharmaceuticals used with imaging procedures such as single-photon emission computed tomography and positron emission tomography. The draft guidance is not intended to apply to possible therapeutic uses of these agents or to in vitro diagnostic products.

Description: The draft guidance is intended to assist developers of drug and biological products used for medical imaging in planning and coordinating the clinical investigations of, and submitting various types of applications for, such products. The draft guidance provides information on how the agency will interpret and apply provisions of the existing regulations regarding the content and format of an application for approval of a new drug (21 CFR 314.50) and the content of a biological product application (21 CFR 601.25). The draft guidance also provides information on how the agency will interpret and apply the final rule on the evaluation and approval of in vivo radiopharmaceuticals used for diagnosis and monitoring (64 FR 26657). The final rule, by adding part 315 (21 CFR part 315), clarifies requirements for the evaluation and approval of drug and biological radiopharmaceuticals under the authority of the act and the PHS Act.

Existing regulations, which appear primarily in parts 314 and 601 (21 CFR parts 314 and 601), specify the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of new drugs and biological products. This information is usually submitted as part of a new drug application (NDA) or a biological license application, or as a supplement to an approved application. Part 315 contains regulations that clarify what information is relevant for diagnostic radiopharmaceuticals. This revised draft guidance supplements these regulations. Under part 315 and the revised draft guidance, information required under the act and the PHS Act to establish safety and effectiveness would still have to be reported.

Description of Respondents: Developers of medical imaging drugs and biological products, including contrast drug products and diagnostic radiopharmaceuticals.

Burden Estimate: The final rule on in vivo radiopharmaceuticals used for