Dated: September 8, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–24556 Filed 9–11–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0389]

Agency Information Collection Activities: Proposed Collection; Comment Request; Notification of a Health Claim or a Nutrient Content Claim Based on an Authoritative Statement; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of August 13, 1998 (63 FR 43400). The document announced an opportunity for public comment on a proposed collection of information; specifically, comments on the submission of notifications of health claims or nutrient content claims based on authoritative statements of scientific bodies. The notice published with two errors. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In FR Doc. 98–21796, appearing on page 43400 in the **Federal Register** of Thursday, August 13, 1998, the following corrections are made:

1. On page 43400, in the third column, in the sixth line from the bottom ''0910–0347—Extension)'' is corrected to read ''0910–0374—Extension)''.

2. On page 43401, in the first column, beginning in the fourth line, ''of a scientific body of the Federal Government or the National Academy of Sciences. Under these sections of the act, a food producer that intends to use such a claim must submit a notification of its intention to use the claim 120 days before it begins marketing'' is corrected to read ''of certain scientific bodies of the Federal Government or of the National Academy of Sciences or any of its subdivisions. Under these sections of the act, a food producer may use such a claim in the labeling of an appropriate product 120 days after a complete notification of the claim is submitted to FDA.''

Dated: September 2, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–24498 Filed 9–11–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0373]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; FDA Recall Regulations

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 (the PRA).

DATES: Submit written comments on the collection of information by October 14, 1998.

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: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration,5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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

FDA Recall Regulations—Part 7 (21 CFR Part 7), Subpart C—(OMB Control Number 0910–0249—Extension)

These regulations were established to provide guidance to manufacturers on recall responsibilities. These responsibilities include development of a recall strategy; providing complete details of the recall reason, risk evaluation, quantity produced, distribution information, firm's recall strategy and a contact official; notifying direct accounts of the recall and to provide recipients with a ready means of reporting to the recalling firm; provide periodic status reports so FDA can assess the progress of the recall. The recall provisions provide the information necessary for FDA to monitor recalls and assess the adequacy of a firm's efforts in a recall. It also permits FDA to evaluate whether a recall has been completed in a manner that assures that unreasonable risk of substantial harm to the public health has been eliminated. The guidelines apply to all regulated products (i.e., food, including animal feed; drugs, including animal drugs; medical devices, cosmetics; and biological products intended for human use.

In the **Federal Register** of June 9, 1998 (63 FR 31502), the agency requested comments on the proposed collections of information. No significant 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 Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
7.42	1,712	1	1,712	1.8	3,082
7.46 and 7.49	1,712	1	1,712	4	6,848
7.53	1,712	1	1,712	36	61,632
7.55(b)	1,712	1	1,712	2	3,424
Totals					74,986

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