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Submission Date	5/6/99
Approval Date	5/7/99
Certifier	<i>[Signature]</i>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-0124]

Agency Information Collection Activities; Submission for OMB Review; Comment Request and Correction; Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

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). In addition, this document is correcting the information collection notice that appeared in the **Federal Register** of February 9, 1999 (64 FR 6364).

DATES: Submit written comments on the collection of information by *(insert date 30 days after date of publication in the Federal Register)*.

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: 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 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.

Premarket Notification for a New Dietary Ingredient—21 CFR 190.6 (OMB Control Number 0910–0330—Extension)

Description: Section 413(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350b(a)) provides for the notification of the Secretary of Health and Human Services (the Secretary) (and by delegation FDA) at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient. The agency established 21 CFR 190.6 as the procedural regulation for this program. This regulation provides details of the administrative procedures associated with the submission and identifies the information that must be included in the submission in order to meet the requirements of section 413(a) of the act and to show the basis on which a manufacturer or distributor of a new dietary ingredient or a dietary supplement containing a new dietary ingredient has concluded that the dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

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

In the **Federal Register** of February 9, 1999 (64 FR 6364), the agency requested comments on the proposed collections of information. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
190.6	11	1	11	20	220

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

The agency believes that there will be a minimal burden on the industry to generate data to meet the requirements of the premarket notification program because the agency is requesting only that information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing a new dietary ingredient is in full compliance with the act. However, the agency estimates that extracting and summarizing the relevant information from the company's files, and presenting it in a format that will meet the requirements of section 413 of the act, will require a burden of approximately 20 hours of work per submission. This

estimate is based on the average number of premarket notifications received by the agency in the last 3 years.

Additionally, in FR Doc. 99-3014, appearing on page 6364 in the **Federal Register** of Tuesday, February 9, 1999, the following correction is made:

1. On page 6365, in the first column, the title “New Dietary Ingredient Premarket Notification—21 CFR 190.6 (OMB Control Number 0910-0330—Extension)” is corrected to read “Premarket Notification for a New Dietary Ingredient—21 CFR 190.6 (OMB Control Number 0910-0330—Extension)”

Dated: 4/29/99

April 29, 1999

William K. Hubbard

William K. Hubbard
Associate Commissioner for Policy Coordination

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F