personal belongings or items used for the purpose of presentation.

Individuals requiring sign language interpretation or other special accommodation must contact the DFO via the contact information specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date listed in the **DATES** section of this notice.

Authority: (Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, section 10(a)).)

Dated: April 4, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–8231 Filed 4–24–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: State Plan for Child Support under Title IV–D of the Social Security Act (OCSE–100 and OCSE–21–U4).

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Plan (OCSE–100)	54	1	0.5	216
OCSE–21–U4	54	1	0.25	108

Estimated Total Annual Burden Hours: 324.

Additional Information: Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: April 15, 2008.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. E8–9040 Filed 4–24–08; 8:45 am]

BILLING CODE 4184–01–M

OMB No.: 0970–0017.

Description: The State plan preprint pages and amendments serve as a contract between the Office of Child Support Enforcement and State and Territory IV–D agencies. These State plan preprint pages and amendments outline the activities States and Territories will perform as required by law, in Section 454 of the Social Security Act, in order for States and Territories to receive Federal funds to meet the costs of child support enforcement.

Respondents: State and Territory IV–D Agencies.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0030] (formerly Docket No. 2004D–0466)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act

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 May 27, 2008.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title, ''Draft Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Draft Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act—(OMB Control Number 0910–NEW)

Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(6)) requires that a manufacturer of a dietary supplement making a nutritional deficiency, structure/function, or general well-being claim have substantiation that the statement is truthful and not misleading. The draft guidance document entitled ''Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act'' (November 9,

2004; 69 FR 64962) is intended to describe the amount, type, and quality of evidence FDA recommends a dietary supplement manufacturer have to substantiate a claim under section 403(r)(6) of the act. The draft guidance does not discuss the types of claims that can be made concerning the effect of a dietary supplement on the structure or function of the body, nor does it discuss criteria to determine when a statement about a dietary supplement is a disease claim. Persons with access to the Internet may obtain the draft guidance at the following Web site: *http://www.cfsan.fda.gov/~dms/guidance.html*. A copy of the draft guidance also is available for public examination in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

In the **Federal Register** of January 28, 2008 (73 FR 4875), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Claim Type	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
Widely known, established	667	1	667	44	29,348
Pre-existing, not widely established	667	1	667	120	80,040
Novel	667	1	667	120	80,040
Total					189,428

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

Dietary supplement manufacturers will only need to collect information to substantiate their product's nutritional deficiency, structure/function, or general well-being claim if they chose to place a claim on their product's label. Gathering evidence on their product's claim is a one time burden; they collect the necessary substantiating information for their product as required by section 403(r)(6) of the act.

The standard discussed in the draft guidance for substantiation of a claim on the labeling of a dietary supplement is consistent with standards set by the Federal Trade Commission for dietary supplements and other health-related products that the claim be based on competent and reliable scientific evidence. This evidence standard is broad enough that some dietary supplement manufacturers may only need to collect peer-reviewed scientific journal articles to substantiate their claims; other dietary supplement manufacturers whose products have properties that are less well documented may have to conduct studies to build a body of evidence to support their claims. It is unlikely that a dietary supplement manufacturer will attempt to make a claim when the cost of obtaining the evidence to support the claim outweighs the benefits of having the claim on the product's label. It is likely that manufacturers will seek substantiation for their claims in the scientific literature.

The time it takes to assemble the necessary scientific information to support their claims depends on the product and the claimed benefits. If the product is one of several on the market making a particular claim for which there is adequate publicly available and widely established evidence supporting the claim, then the time to gather supporting data will be minimal; if the product is the first of its kind to make a particular claim or the evidence supporting the claim is less publicly available or not widely established, then gathering the appropriate scientific evidence to substantiate the claim will be more time consuming.

FDA assumes that it will take 44 hours to assemble information needed to substantiate a claim on a particular dietary supplement when the claim is widely known and established. We increased this estimated burden from 1 hour per claim to 44 hours per claim based on information received from industry, as noted in our June 7, 2007, document in response to comment 1 (72 FR 31583 and 31584). FDA believes it will take closer to 120 hours to assemble supporting scientific information when the claim is novel or when the claim is pre-existing but the scientific underpinnings of the claim are not widely established. These are claims that may be based on emerging science, where conducting literature searches and understanding the literature takes time. It is also possible that references for claims made for some dietary ingredients or dietary supplements may primarily be found in foreign journals and in foreign languages or in the older, classical literature where it is not available on computerized literature databases or in the major scientific reference databases, such as the National Library of Medicine's literature database, all of which increases the time of obtaining substantiation.

In the **Federal Register** of January 6, 2000, FDA published a final rule on statements made for dietary supplements concerning the effect of the product on the structure or function of the body (65 FR 1000). FDA estimated that there were 29,000 dietary supplement products marketed in the United States (65 FR 1000 at 1045). Assuming that the flow of new products is 10 percent per year, then 2,900 new dietary supplement products will come on the market each year. The structure/function final rule estimated that about 69 percent of dietary supplements have a claim on their labels, most probably a structure/function claim (65 FR 1000 at 1046). Therefore, we assume that supplement manufacturers will need time to assemble the evidence to substantiate each of the 2,001 claims ($2{,}900 \times 69$ percent) made each year. If we assume that the 2,001 claims are equally likely to be pre-existing widely established claims, novel claims, or pre-existing claims that are not widely established, then we can expect 667 of each of these types of claims to be substantiated per year. Table 1 of this document shows that the annual burden hours associated with assembling evidence for claims is 189,428 (the sum of 667×44 hours, 667×120 hours, and 667×120 hours).

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

Dated: April 17, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–8973 Filed 4–24–08; 8:45 am]

BILLING CODE 4160–01–S