Harmonized System of Classification and Labeling of Chemicals (GHS), the EPA, and the European Union hazard classification systems. NICEATM and ICCVAM prepared a comprehensive background review document (BRD) on each of the four *in vitro* test methods. Each BRD included an analysis of test method performance (i.e., reliability and relevance) as compared to the *in vivo* rabbit eye reference test method, based on all available data. ICCVAM developed recommendations on the usefulness and limitations of these *in vitro* test methods for identifying ocular corrosives/severe irritants after considering the BRDs, comments received from the public and the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM), and comments and recommendations received from an independent expert panel (**Federal Register** Vol. 70, No. 53, pp 13513–13514, March 21, 2005 and Vol. 70, No. 211, p 66451, November 2, 2005).

ICCVAM is now reviewing the validation status of these and other *in vitro* test methods for identifying nonsevere ocular irritants (i.e., those that induce reversible ocular damage) and non-irritants.

Request for Data

As part of the review process, NICEATM requests the submission of data from substances tested for ocular irritancy in humans, rabbits, and/or *in vitro*. Data received by July 23, 2007 will be compiled and added to the database maintained by NICEATM and utilized where appropriate in the evaluation of *in vitro* ocular irritation test methods. Data received after this date will also be considered and used where applicable for future evaluation activities. All information submitted in response to this notice will be made publicly available upon request to NICEATM.

When submitting substance and protocol information/test data, please reference this **Federal Register** notice and provide appropriate contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, as applicable).

NICEATM prefers data to be submitted as copies of pages from study notebooks and/or study reports, if available. Raw data and analyses available in electronic format may also be submitted. Each submission for a substance should preferably include the following information, as appropriate:

- Common and trade name.
- Chemical Abstracts Service Registry Number (CASRN).
- Chemical and/or product class.
- Commercial source.
- *In vitro* test protocol used.
- Rabbit eye test protocol used.
- Human eye test protocol used.
- Individual animal/human or *in vitro* responses at each observation time (i.e., raw data).
- The extent to which the study complied with national/international Good Laboratory Practice (GLP) guidelines.
- Date and testing organization.

Additional information on the submission of data may be obtained at *http://iccvam.niehs.nih.gov/methods/ocutox/ivocutox.htm.*

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from 15 federal regulatory and research agencies that use or generate toxicological information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological test methods that more accurately assess the safety and hazards of chemicals and products and that refine, reduce, or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l–3, available at *http://iccvam.niehs.nih.gov/docs/about_docs/PL106545.pdf*) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers the ICCVAM and provides scientific and operational support for ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of federal agencies. Additional information about ICCVAM and NICEATM is available on the following Web site: *http://iccvam.niehs.nih.gov.*

Dated: May 25, 2007.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences and National Toxicology Program.

[FR Doc. E7–10966 Filed 6–6–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institution for Occupational Safety and Health (NIOSH) Advisory Board on Radiation and Worker Health (ABRWH or Advisory Board)

Correction: This notice was published in the **Federal Register** on May 22, 2007, Volume 72, Number 98, pages 28697–28698. The meeting was originally scheduled to be held at the Westin Westminster Hotel. The Committee will now convene at the Sheraton Denver West Hotel, 360 Union Boulevard, Lakewood, Colorado 80228, Phone 303.987.2000, Fax 303.969.0263.

Times and Dates:

9 a.m.–5 p.m., June 11, 2007.

8 a.m.–3 p.m., June 12, 2007.

Contact Person for More Information: Dr. Lewis V. Wade, Executive Secretary, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, Telephone 513.533.6825, Fax 513.533.6826.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: May 31, 2007.

Elaine L. Baker,

Acting Director, Management Analysis and Services Office Centers for Disease Control and Prevention.

[FR Doc. E7–10987 Filed 6–6–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0466]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 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 July 9, 2007.

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. All comments should be

identified with the OMB control number ''0910–NEW'' and title, ''Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of 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.

Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of 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'' 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. This 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.

In the **Federal Register** of November 9, 2004 (69 FR 64962), FDA published a Notice of Availability of the draft guidance document with a 60-day notice requesting public comment on the collection of information provisions. We received a number of letters containing one or more comments, several of which responded to our request for comments on the proposed information collection.

(Comment 1) Several comments challenged the accuracy of the estimated number of hours it would take to prepare the information needed to substantiate a claim when that claim is widely known and accepted. We estimated it would take 1 hour because supporting material for such claims should be readily available in textbooks and reference books. Two comments asserted that the burden estimate was too low but did not propose an alternative estimate or provide information to support a higher estimate. One comment did provide such information. Based on a review of how long it took to assemble the supporting information for approximately 50 claims involving products containing from 1 to 3 herbs, the comment stated that, for these claims, it took 18 to 24 hours to assemble the supporting information and an additional 2 to 4 hours to have a qualified expert review the information. In addition, the comment stated that, for products with more complicated formulations, it took approximately 40 hours plus the expert review time to assemble the supporting information.

(Response) FDA has considered the information provided in the comment. Based on this information, we have increased our estimate of the burden of preparing the information needed to substantiate a claim on a dietary supplement when the claim is widely known and accepted from 1 hour to 44 hours.

(Comment 2) One comment disagreed with our statement that there are no capital, operating, or maintenance costs associated with this collection of information. The comment stated that they use staff support, copying and scanning equipment, and electronic and hard copy file storage when preparing substantiation files. The comment also stated that there is a capital cost to maintain a botanical library collection of historical references and current scientific journals. Finally, it stated there is an on-going cost associated with reviewing scientific literature for new scientific developments.

(Response) FDA believes that it is accurate to state that there are no capital, operating, or maintenance costs associated with this collection of information. Collecting the required information may generate some capital costs associated with using electronic equipment such as scanners and computers and using hard-copy file cabinets. However, we estimate that this cost is negligible because most firms probably already have this equipment, and the incremental cost of using this equipment for the purposes described would be very small. The few firms that do not own the necessary equipment could pay for access to scanners and computers for a minimal charge. Operating costs for this equipment would consist of the incremental cost of electricity for this equipment during the time it was used for the purposes described. Maintenance costs for this equipment would consist of the overall maintenance costs pro rated for the time the equipment was used for the purposes described. Both operating and maintenance costs would be minimal. Personnel costs associated with using this equipment have already been included as part of the burden hours that we presented in table 1 of this document. Further, we do not agree with the comment's assertion that a respondent would need to maintain a botanical library collection of historical references and current scientific journals. It is not necessary for a respondent to maintain a Botanical Library in order to access the requested information. In addition, the guidance does not recommend the firms continually update supporting material. We do not agree that the on-going cost of reviewing scientific literature for new scientific developments is a cost of this information collection. Therefore, FDA has not changed its assessment that there are no capital, operating, or maintenance costs associated with this collection of information.

FDA estimates the burden for this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL ONE-TIME 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

TABLE 1.—ESTIMATED ANNUAL ONE-TIME REPORTING BURDEN[1]—Continued

Claim type	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total					189,428

[1] There are no capital 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 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 response to comment 1. 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 final rule on statements made for dietary supplements concerning the effect of the product on the structure or function of the body (structure/function final rule (65 FR 1000, January 6, 2000)), 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 x 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 x 44 hours, 667 x 120 hours, and 667 x 120 hours).

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

Dated: May 31, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–10911 Filed 6–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0201]

Determination That CEFOTAN (Cefotetan Disodium For Injection), Equivalent 1 Gram Base/Vial and 2 Grams Base/Vial, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that CEFOTAN (cefotetan disodium for injection), equivalent 1 gram (g) base/vial and 2 g base/vial, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for cefotetan disodium for injection, equivalent 1 g base/vial and 2 g base/vial, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nam Kim, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–443–5537.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,''