

The following additional requirements are applicable to this program. For a complete description of each, see Attachment III in the application kit.

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-7 Executive Order 12372 Review
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-17 Peer and Technical Reviews of Final Reports of Health Studies—ATSDR
- AR-18 Cost Recovery—ATSDR
- AR-19 Third Party Agreements—ATSDR

**J. Where To Obtain Additional Information**

A complete copy of the announcement may be downloaded from CDC's home page at: <http://www.cdc.gov> Click on "Funding" then "Grants and Cooperative Agreements."

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Edna Green, Grants Management Specialist, Acquisition and Assistance Branch B, Procurement and Grants Office, Centers for Disease Control and Prevention, Announcement 02134, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone number (770) 488-2743, E-mail address: [ecg4@cdc.gov](mailto:ecg4@cdc.gov).

For program technical assistance, contact: Kevin Horton, Epidemiologist, Division of Health Studies, Agency for Toxic

Substances and Disease Registry, Executive Park, Building 4, Suite 2300, MS E-31, Atlanta, GA 30305, Telephone: (404) 498-0571, E-mail Address: [Dhorton@CDC.GOV](mailto:Dhorton@CDC.GOV).

or Maggie Warren, Public Health Advisor, Division of Health Studies, Agency for Toxic Substances and Disease Registry, 1600 Clifton Rd., NE., MS E-31, Atlanta, GA 30333, Telephone (404) 498-0546, E-mail Address: [mcs9@cdc.gov](mailto:mcs9@cdc.gov).

Dated: June 3, 2002.

**Edward Schultz,**

*Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[Program Announcement 02073]

**Traumatic Brain Injury (TBI) Follow-up Registry And Surveillance of TBI in the Emergency Department (ED); Notice of Availability of Funds; Amendment**

A notice announcing the availability of Fiscal Year 2002 funds to fund grants for Traumatic Brain Injury Follow-up Registry And Surveillance Of TBI In The Emergency Department was published in the **Federal Register** on May 8 2002, Vol. 67, No. 89, pages 30939-30942. The notice is amended as follows:

On page 30939, first column, Section C. Availability of Funds, Paragraph 1, line 1, should be changed to read "\* \* \* Approximately \$715,000

(including direct and indirect cost)  
\* \* \*

Dated: June 4, 2002.

**Edward Schultz,**

*Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*

[FR Doc. 02-14451 Filed 6-7-02; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

*Proposed Projects:*

*Title:* Form OCSE-396A: Financial Report; Form OCSE-34A: Quarterly Report of Collections.

*OMB No.:* 0970-0181.

*Description:* Each State agency administering the Child Support Enforcement Program under Title IV-D of the Social Security Act is required to provide information to the Office of Child Support Enforcement concerning its administrative expenditures and its receipt and disposition of child support payments from non-custodial parents. These quarterly reporting forms enable each State to provide that information, which is used to compute both the quarterly grants awarded to each State and the annual incentive payments earned by each State. This information is also included in a published annual statistical and financial report, available to the general public.

*Respondents:* State agencies administering the Child Support Enforcement Program.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Average burden hours
OCSE-396A .....	54	4	8	1,728
OCSE-34A .....	54	4	8	1,728
Estimated Total Annual Burden Hours: .....				3,456

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing

to the Administration for Children and Families, 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.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary

for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: June 4, 2002.

**Bob Sargis,**

*Reports Clearance Officer.*

[FR Doc. 02-14464 Filed 6-7-02; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 02N-0062]

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

**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 July 10, 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.

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

Section 413(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350b(a)) provides that a manufacturer or distributor of dietary supplements or of a new dietary ingredient is to submit information to FDA (as delegate for the Secretary of Health and Human Services) upon which it has based its conclusion that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient. FDA's regulations at part 190, subpart B (21 CFR part 190, subpart B) implement these statutory provisions. Section 190.6(a) requires each manufacturer or distributor of a dietary supplement

containing a new dietary ingredient, or of a new dietary ingredient, to submit to the Office of Nutritional Products, Labeling, and Dietary Supplements notification of the basis for their conclusion that said supplement or ingredient will reasonably be expected to be safe. Section 190.6(b) requires that the notification include: (1) The complete name and address of the manufacturer or distributor, (2) the name of the new dietary ingredient, (3) a description of the dietary supplements that contain the new dietary ingredient, and (4) the history of use or other evidence of safety establishing that the dietary ingredient will reasonably be expected to be safe.

The notification requirements described previously are designed to enable FDA to monitor the introduction into the food supply of new dietary ingredients and dietary supplements that contain new dietary ingredients, in order to protect consumers from unsafe dietary supplements. FDA uses the information collected under these regulations to help ensure that a manufacturer or distributor of a dietary supplement containing a new dietary ingredient is in full compliance with the act.

In the **Federal Register** of March 19, 2002 (67 FR 12570), the agency requested comments on the proposed collection of information. One comment was received, but it did not pertain to the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
190.6	35	1	35	20	700

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA believes that there will be minimal burden on the industry to generate data to meet the requirements of the premarket notification program because FDA 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 annual average number of premarket notifications FDA received during the last 3 years (i.e., 1999-2001), which was 23. Twenty-three represents 12 more notifications than the agency received as an annual average during the previous 3-year period (i.e., 1996-1998). Therefore, FDA anticipates a similar upward trend will be seen in the annual average number of notifications it receives during 2002-2004, which is estimated to be 35 (23 + 12 = 35).

Dated: May 31, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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