

Dated: September 8, 1998.

**Bob Sargis,**

*Acting Reports Clearance Officer.*

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

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## 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]

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## 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 <sup>1</sup>

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

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

Due to a typographical error, the "Annual Frequency per Response" for 21 CFR 7.42, 7.46 and 7.49, 7.53, and 7.55(b) were reported as "4" in FDA's June 9, 1998, notice providing 60 days for public comment on this collection of information. Therefore, the totals for "Total Annual Responses" and "Total Hours" were reported incorrectly. Table 1 of this document reflects the correct annual frequency per response, total annual responses and total burden hours.

Dated: September 3, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98-24496 Filed 9-11-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Cooperative Agreements With National HIV/AIDS Organizations

**AGENCY:** Health Resources and Services Administration.

**ACTION:** Notice of limited competition for cooperative agreements with national HIV/AIDS organizations.

**SUMMARY:** The Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB) announces a limited competition to support the development and performance of specialized technical assistance activities for HRSA's HIV/AIDS Title IV grantees under Section 2671 of the Public Health Service Act, as amended by the Ryan White CARE Act Amendments of 1996, Public Law 104-146, dated May 20, 1996 (PHS Act), and to support the development of materials and training for AIDS Education and Training Centers under Section 2692 of the PHS Act.

HRSA is limiting competition to three national HIV/AIDS organizations: the National Alliance of State and Territorial AIDS Directors (NASTAD), the National Pediatric & Family HIV Resource Center (NPHRC), and AIDS Policy Center for Children, Youth and Families (APC). In cooperation with HRSA, these three organizations will engage in a number of activities that include technical assistance to Title IV grantees, policy analysis, materials development, and training for HRSA's Ryan White programs. Assistance will be provided only to these three organizations. No other applications are solicited, nor will they be accepted.

These three organizations are the only qualified entities to provide the services specified under this cooperative agreement because:

1. NASTAD is the only officially established organization that represents the State and Territorial AIDS Directors in all 50 States and all U.S. Territories. As such, it represents the officials from throughout the U.S. who have responsibility for designing, implementing, and evaluating HIV/AIDS service programs for uninsured and underinsured populations. In addition, NASTAD has already established mechanisms for communicating HIV/AIDS information to States and the political subdivisions of the States that implement HRSA's CARE Act programs.

2. NPHRC is uniquely qualified to assure the provision of effective technical assistance through its clinical experience and capacity in promoting the organization and maintenance of comprehensive, coordinated care that is linked to research for children, youth, women and families affected by HIV/AIDS. As a HRSA supported national resource center, NPHRC and its clinical staff has unique access to providers throughout the U.S. to assure the needs of this population are addressed across all venues.

3. APC has extensive knowledge and experience in assessing adolescent AIDS comprehensive care policy. The organization has considerable credibility among existing adolescent clinical care providers, researchers and consumers and a demonstrated in-depth understanding of the Ryan White CARE Act.

#### Grants/Amounts

Approximately \$600,000 is available in fiscal year (FY) 1998 for a 12-month budget period with a project period of 3 years for these three organizations. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

**FOR FURTHER INFORMATION CONTACT:** Additional information may be obtained from Ms. Angela Powell-Young, Chief, Technical Assistance Branch, Division of Training and Technical Assistance, HIV/AIDS Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 7-13, Rockville, Maryland 20857. The telephone number is (301) 443-9091 and the fax number is (301) 594-2835.

Dated: September 4, 1998.

**Claude Earl Fox,**

*Administrator.*

[FR Doc. 98-24557 Filed 9-11-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration (HRSA)

#### HRSA AIDS Advisory Committee Care Act Reauthorization Workgroup

**AGENCY:** Health Resources and Services Administration (HRSA).

**ACTION:** Notice of public meeting and opportunity to provide written comments.

**SUMMARY:** On December 2, 1997, the HRSA AIDS Advisory Committee (HAAC) established the Ryan White CARE Act Reauthorization Workgroup. The workgroup is seeking public input about future HIV/AIDS care program directions including issues related to the second reauthorization of the Ryan White CARE Act. The HAAC will subsequently submit a set of formal recommendations relating to future program directions and reauthorization issues to the HRSA Administrator.

**DATES:** A public meeting will be held on October 9, 1998, from 8:30 a.m. to 5:00 p.m., to obtain public input into future program directions and issues related to the reauthorization of the Ryan White CARE Act of 1990 as amended by the Ryan White CARE Act Amendments of 1996 (Pub L. 104-146). To be assured of consideration for this public session, written comments should be postmarked no later than October 23, 1998, and should contain the name, address, telephone and fax numbers and any organizational affiliation of the persons requesting to provide a written statement. The public meeting will be held at the Crowne Plaza St. Anthony Hotel, 300 East Travis, San Antonio, Texas, 78205; phone (210) 227-4392; FAX (210) 227-0915.

**ADDRESSES:** Written comments should be sent to the HRSA AIDS Advisory Committee, c/o HRSA HIV/AIDS Bureau, Office of Policy and Program Development, Attention: Caitlin Ryan, Parklawn Building, 5600 Fishers Lane, Room 7-20, Rockville, Maryland 20857.

All requests for making oral comments will be made at the meeting on October 9, 1998. Depending on the number of requests to present oral comments, it may be necessary to limit the length of time for each presenter.