

process, and eventual publication in both the *Journal of AOAC International* and OMA. AOAC International's existence as an internationally recognized organization means that AOAC International official methods are internationally acceptable based on the association's prior efforts to "harmonize" standards of acceptability. Methods are developed and subjected to interlaboratory collaborative study by Associate Referees, under the guidance of General Referees and the Official Methods Board and its Committees. AOAC International staff and methods committee members assist in recruiting laboratories with appropriate expertise to participate in approved collaborative studies. Volunteer statisticians assigned to the Committee by AOAC International assist the Associate Referee in evaluating study results. If the statistical evaluation of analytical results demonstrates that the method is capable of producing accurate and precise results in multiple laboratories, it is recommended for official status. After assenting mail vote by the association, the description of the newly approved official method is incorporated by the editorial staff into the next annual revision of OMA; details of the collaborative study are published in the *Journal of AOAC International*.

AOAC International conducts an annual international meeting, which includes presentation of symposia, reports methods and collaborative studies, and deliberation decisions by the Official Methods Board and its Committees.

### III. Substantive Involvement by the FDA

FDA supports AOAC International under this cooperative agreement because the existence of AOAC International and its programs benefits both FDA and other regulators monitoring regulated products; regulated industries benefit equally from these activities. The availability of validated methods also benefits FDA-regulated industry which needs validated analytical methods to comply with regulatory requirements under the Federal Food, Drug, and Cosmetic Act. Beyond the financial support, this agreement also commits FDA's personnel to participation in the scientific and administrative operations of AOAC International.

Members of AOAC International are chemists, microbiologists, toxicologists and others engaged in the analysis of foods, animal feeds, drugs, agricultural commodities and environmental matrixes. Members identify and develop methods to be tested and organize the

interlaboratory validation studies. Members receive and review the results of validation studies. Members receive and review methods recommendations, and members study, devise and recommend policies and protocols addressing methods, validation studies, quality assurance, safety and statistical analysis.

FDA involvement in AOAC International activities continues at a high level, with a significant percentage of Associate and General Referee and Committee positions filled by FDA personnel. Any laboratory or individual may participate in the development, testing, and collaborative study of new or improved methods. The international voluntary participation among scientists in government, academic, and industry laboratories enhances the credibility and acceptability of methods and saves time and money through shared efforts and costs.

### IV. Review Procedure

This application will undergo dual peer review. An ad hoc review panel of experts will review and evaluate the application based on its scientific merit. A second level review will be conducted by the National Advisory Environmental Health Sciences Council.

### V. Mechanism of Support

#### A. Award Instrument

Support for this program, if granted, will be in the form of a cooperative agreement. In 1998, FDA is providing approximately \$100,000 for this award. The award will be subject to all policies and requirements that govern the research grant programs of the Public Health Service (PHS), including the provisions of 42 CFR part 52, 45 CFR part 74, and the PHS Grants Policy Statement.

#### B. Length of Support

The length of support will be one (1) year with the possibility of an additional four (4) years of noncompetitive support. Continuation, beyond the first year, will be based upon performance during the preceding year and the availability of Federal fiscal year appropriations.

#### C. Memorandum of Understanding (MOU)

FDA and AOAC International will develop a MOU to cover and clarify AOAC International's publication of FDA manuals.

### VI. Reporting Requirement

Program progress reports and financial status reports will be required annually, based on date of award. These reports will be due within 30 days after

the end of the budget period. A final program progress report and financial status report will be due 90 days after expiration of the project period of the cooperative agreement.

### VII. Application Due Date

Applications should be submitted to Robert L. Robins (address above) by January 6, 1998.

Dated: December 16, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 97N-0160]

### Agency Information Collection Activities; Announcement of OMB Approval

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Food Labeling: Nutrient Content Claims and Health Claims; Restaurant Foods" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**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:** On September 17, 1997, the agency submitted the proposed information collection to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0349. The approval expires on November 30, 2000.

Dated: December 10, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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