While the Commissioner does not need to reach the issue of whether FDA's decision not to provide further opportunity to demonstrate or achieve compliance was proper under § 601.5, he notes that § 601.5 requirements have been satisfied because Plascon's conduct was willful within the meaning of § 601.5. Courts that have considered the meaning of willfulness in the context of license revocation proceedings have noted that willful conduct can be found when a person acts with careless disregard of statutory requirements. (See, e.g., *Potato Sales Co., Inc.* v. *United States Dept. of Agric.*, 92 F.3d 800, 805 (9th Cir. 1996); *Cox* v. *United States Dept. of Agric.*, 925 F.2d 1102, 1105 (8th Cir. 1991), *cert. denied*, 502 U.S. 860 (1991); *Lawrence* v. *Commodity Futures Trading Corp.*, 759 F.2d 767, 773 (9th Cir. 1985); *Finer Food Sales Co.* v. *Block*, 708 F.2d 774, 778 (D.C. Cir. 1983); *American Fruit Purveyors Inc.* v. *United States*, 630 F.2d 370, 374 (5th Cir. 1980), *cert. denied*, 450 U.S. 997 (1981).) Plascon's pattern of continued noncompliance with the applicable license standards and regulations, despite ample notice from the FDA of the firm's noncompliance and repeated assurances from Plascon that the firm would come into compliance, demonstrates careless disregard of the applicable requirements. Thus, the agency finds that Plascon's conduct was willful within the meaning of § 601.5, and thus it was not necessary to provide Plascon with further opportunity to demonstrate or achieve compliance.

The next issue for consideration is whether the data and information Plascon submitted raise a genuine and substantial issue of fact for resolution at a hearing (§ 12.24(b)(1).) FDA's proposed revocation of Plascon's establishment and product licenses is based on Plascon's failure to adhere to the applicable regulations and the standards in Plascon's license application, not on a finding that these failures constitute a ''danger to health.'' (Letter from FDA to Plascon, May 5, 1994, at p. 1–3; 60 FR 57719.) FDA's focus on Plascon's failure to comply with the applicable regulations and standards conforms to the applicable regulations. (See § 601.5(b)(4).)

The grounds for revocation set forth in § 601.5(b)(4) have been established in this case. As described above, FDA's inspections documented Plascon's deviations from the applicable regulations and standards during four inspections between 1989 and 1993. Plascon has not only failed to submit any data and information challenging FDA's inspectional findings, but also has admitted that the firm failed to comply with the applicable regulations. Indeed, by the firm's own characterization, the conditions observed during the 1993 inspection, which led to the suspension and proposed revocation of Plascon's licenses, were ''deplorable.'' (See Letter from Plascon to FDA, June 29, 1994, at p. 3 (''[I]t is a source of great regret'' that the:

> conditions observed by FDA investigators * * * during the[] December 13–17, 1993 inspection of [Plascon] were so deplorable, resulting in the issuance of a Form FDA–483 with 66 inspectional observations * * * [T]he facility was not operating in an acceptable manner, and [Plascon] accepts full responsibility for that extremely unfortunate situation.);

see also *id.* at p. 2 (''Without for a moment seeking to justify or minimize the deviations from regulatory requirements that were observed during the various FDA inspections over the more than four year period of time * * *''); *id.* at p. 25 (''The final inspection, in December of 1993, was by far the 'worst' of these inspections * * *''); *id.* at 28 (''*if* the December 1993 inspection had been a completely successful one, instead of the disaster that it obviously was * * *''); Letter from Plascon to FDA dated February 21, 1994, Corrective Action Plan, at p. 2 (''Plascon, Inc. has terminated employees who were not following proper protocol during the most recent FDA inspection.'').)

Having conceded the existence of the ''deplorable'' conditions at Plascon, the firm confines its challenge to the proposed revocation of its licenses to whether FDA established the existence of a danger to health when the agency suspended Plascon's licenses on May 5, 1994. More specifically, Plascon argues that the regulatory deficiencies observed did not affect the quality of the Source Plasma manufactured by the firm and that FDA has not established the existence of a ''danger to health.'' (Letter from Plascon to FDA dated January 12, 1996, at p. 1.) However, while the issue of whether the Commissioner had reasonable grounds to believe that by reason of the existence of the grounds for revocation of Plascon's licenses there was ''a danger to health'' was relevant to the decision to *suspend* the firm's licenses, it has no bearing on the *revocation* of those licenses under § 601.5(b).

Plascon's hearing request will be granted only if the material submitted shows that there is a genuine and substantial issue of fact for resolution at a hearing (§ 12.24(b)(1)). A hearing will not be granted on factual issues that are not determinative with respect to the action requested (§ 12.24(b)(4)). As the District of Columbia Circuit Court of Appeals observed, ''Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted.'' *Copanos & Sons* v. *FDA*, 854 F.2d 510, 523 (D.C. Cir. 1988). Plascon's hearing request raises only an irrelevant factual dispute, the resolution of which, even if in Plascon's favor, would have no bearing on the merits of the revocation of its licenses.

For the reasons set forth above, the agency finds that Plascon, Inc., doing business as Anderson Plasma Center, has failed to show that there is a genuine and substantial issue of fact justifying a hearing on the revocation of its establishment and product licenses. The agency also finds that significant deviations from the biologics regulations and the standards set forth in the firm's licenses existed which warrant revocation of Plascon's licenses. Therefore, under section 351 of the Public Health Service Act (42 U.S.C. 262) and under §§ 12.28, 601.5, and 601.7, the Commissioner denies the request for a hearing and revokes the establishment (U.S. License No. 572–003) and product licenses issued to Plascon, Inc., doing business as Anderson Plasma Center, for the manufacture of Source Plasma.

Dated: December 16, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97–33373 Filed 12–22–97; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Program Announcement Number FDA–CFSAN–98–1 Cooperative Agreement for Validation of Analytical Methods, Standards, and Procedures

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), is announcing its intention to accept and consider a single source application for award of a cooperative agreement to support AOAC International in the amount of $100,000. The cooperative agreement will provide support for the Validation of Analytical Methods, Standards, and Procedures.

**DATES:** Submit applications by January 6, 1998.

**ADDRESSES:** An application is available from and should be submitted to Robert L. Robins (address below). Applications hand carried or commercially delivered should be addressed to the Park Bldg., 12420 Parklawn Dr., rm. 3–40, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Regarding the administrative and financial management aspects of this notice: Robert L. Robins, Grants Management Officer, or Rosemary T. Springer, Grants Management Specialist, Office of Regulatory Affairs Support and Assistance Management Branch, State Contracts and Assistance Agreements Branch (HFA–520), Food and Drug Administration, Park Bldg., 5600 Fishers Lane, rm. 3–40, Rockville, MD 20857, 301–443–6170.

Regarding the programmatic aspects of this program: Bernadette McMahon, Office of Plant and Dairy Foods and Beverages (HFS–337), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4038.

**SUPPLEMENTARY INFORMATION:** FDA is announcing its intention to accept and consider a single source application from AOAC International for supporting the Validation of Analytical Methods, Standards, and Procedures. FDA's authority to enter into grants and cooperative agreements is set out in section 301 of the Public Health Service Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance at section 93.103. Before entering into cooperative agreements, FDA carefully considers the benefits such agreements will provide to the public.

## I. Background

Until 1979, AOAC International operated as part of the U.S. FDA, whose employees performed as Executive Director and Journal Editor, among other positions. At that time, on the recommendation of an independent panel, AOAC International became independent of FDA and was established as a nonprofit association.

Since the separation of FDA and AOAC International, FDA has continued to provide financial support to AOAC International through a cooperative agreement. In the beginning, FDA was motivated to ensure that AOAC International would have funds needed to continue publishing new editions (every 5 years) of *Official Methods of Analysis of AOAC (OMA)*, the compilation of all methods validated through the collaborative process, which is of interest to regulated industry. AOAC International no longer requires FDA's support to underwrite the publication of OMA, which is now AOAC International's main source of revenue. FDA's current support for AOAC International, both financially and with activities of its employees, is motivated by its recognition of AOAC International's critical role in organizing, operating, and maintaining an internationally recognized system for establishing collaborated methods of analysis. It is imperative to FDA that an organization such as AOAC International continue to function efficiently, especially in scientific areas in which internationally recognized analytical methods are required to support regulatory decisions.

AOAC International consists of the following members: A governing board (Board of Directors, including officers) concerned with administration and policy making; Official Methods Board; Editorial Board; special and standing committees which serve in advisory and liaison capacities; other groups concerned with development of methods, publication, and general activities; and the headquarters staff which conducts the day-to-day business.

In recent years, AOAC International has initiated additional activities aimed at the improvement of the analytical sciences, including training programs on critical subjects such as modern analytical technologies, application of quality assurance principles, and statistical principles and applications. The association established a Research Foundation to assess and certify commercial test kits, defined an additional level of validated methods (the ''peer verified'' methods), and is investigating the potential for developing analytical standard reference materials. AOAC International has embraced opportunities to use electronic media to distribute its validated methods and other supporting materials through use of the World Wide Web and CD-ROM formats.

## II. Purpose of Agreement

The primary purpose is to provide financial and scientific support for AOAC International cooperative volunteer system of scientific analytical methods development and approval. This system produces methods that meet predetermined levels of quality for analysis of foods, animal feeds, drugs and cosmetics; such methods are critical to the acceptability of regulatory analytical results performed by FDA and by the regulated industry. AOAC International has excelled in planning, coordinating, and managing the activities essential to developing tested analytical procedures applicable to a wide range of sample types of interest to industry, government, and academia. This is one of very few programs which provide methodology validated through a formal interlaboratory collaborative study process.

To accomplish this overall goal, AOAC International will:

1. Develop standards and criteria for evaluation of results in analytical methods validation, balancing the needs for statistical acceptability, international harmonization, and practicality in an era of shrinking fiscal resources.

2. Identify needs for new and improved analytical methods for food composition and safety, vitamins and nutrients, food additives, pesticide and industrial chemical residues, drug formulations, animal drug residues, cosmetics chemistry and microbiology, color additives and any other products or substances affecting the public health and safety.

3. Recruit and support logistically the volunteer experts necessary to the successful development, review, and testing of needed methods.

4. Apply quality assurance principles to validation studies.

5. Encourage FDA and regulated industry to do more related research in analytical sciences.

6. Sponsor and participate in international forums.

7. Promote wider use of validated methods.

8. Increase opportunities for interaction of FDA-related science in international activities.

AOAC International maintains no laboratories itself, conducts no research, performs no tests. The actual work of developing and testing methods is done by scientists of Federal, State, provincial and municipal regulatory agencies, colleges and universities, commercial firms, and other private laboratories.

AOAC International provides the framework within which the collaborative study process occurs. With AOAC International as a focal point of analytical expertise, sufficient cooperating volunteer members can be found to effect the complex process of testing a method simultaneously in multiple laboratories. AOAC International staff members facilitate logistics required for operations, including the necessary meetings, recruitment of volunteers and collaborating laboratories, the voting

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 Interantional 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.*

[FR Doc. 97–33371 Filed 12–22–97; 8:45 am]

BILLING CODE 4160–01–F

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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.*

[FR Doc. 97–33374 Filed 12-22-97; 8:45 am]

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