

Dated: February 27, 1996.

William K. Hubbard,

Associate Commissioner for Policy  
Coordination.

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[Docket No. 95N-0409]

**Alternative and Traditional Models for Safety Evaluation of Food Ingredients; Announcement of Study; Request for Scientific Data and Information; Announcement of Open Meeting**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) will undertake a comprehensive discussion of the scientific criteria and principles generally agreed upon by scientists in the food safety community as necessary for demonstrating that a food ingredient is safe. This discussion will include both a description of the data needed to ensure safety or to achieve a reasonable certainty that the ingredient will not cause harm and alternative approaches for achieving that assurance when traditional approaches do not definitively resolve safety questions.

To assist in the preparation of a scientific report, LSRO/FASEB is inviting the submission of scientific data and information regarding this topic. LSRO/FASEB will provide an opportunity for oral presentations at an open meeting.

**DATES:** LSRO/FASEB has scheduled a 1-day public meeting on this topic for May 15, 1996. Requests to make oral presentations at the open meeting must be submitted in writing and received by April 24, 1996. Submit written presentations of scientific data, information, and views on or before May 10, 1996.

**ADDRESSES:** Submit written requests to make oral presentations at the open meeting to both the Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20814-3998 and to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Two copies of the scientific data, information, and views for presentation should be submitted to each office. The meeting will be held in the Chen

Auditorium, Lee Bldg., FASEB (address above).

**FOR FURTHER INFORMATION CONTACT:**

Daniel J. Raiten or Sue Ann Anderson, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20814-3998, 301-530-7030, on the scheduling of presentations at the public meeting and related matters. Other information may be obtained from Victor Frattali, Center for Food Safety and Applied Nutrition (HFS-2), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-1730. **SUPPLEMENTARY INFORMATION:** FDA has a contract (223-92-2185) with LSRO/FASEB concerning the analysis of scientific issues that bear on the safety of foods and cosmetics. The objectives of this contract are to provide information to FDA on general and specific issues of scientific fact associated with the analysis of human nutrition.

As one task under the contract, FDA has requested information on matters related to the adequacy of data needed to support decisions on the safety of food ingredients. Currently, FDA provides safety testing guidelines for food ingredients through a publication entitled "Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food" (also known as the "Redbook"). This document gives guidance to petitioners primarily for those situations in which a traditional approach to safety testing is appropriate (i.e., those in which food additives to be used in low concentrations are tested for safety).

However, traditional studies involving administration of substances constituting a large part of an animal's diet may produce adverse effects simply as a result of the unusual diet rather than the inherent toxicity of the test substance. Further, FDA recognizes that the advent of new technologies such as genetic engineering of traditional foods and novel uses of plant products, as well as development of macroingredients, present new situations for which an alternative approach to safety assessment may be needed. While FDA has successfully reached decisions on food ingredients produced with such new technologies on a case-by-case basis, it has become clear that a need exists for information on the criteria that the scientific community believes are appropriate so that both a requirement for new types of safety studies and any elimination or limitation of the role of traditional studies can be justified. Types of food

ingredients for which an alternative model may be appropriate include, for example, macroingredient substitutes such as psyllium, ingredients derived from botanicals such as *Stevia rebaudiana Bertoni*, restructured fats such as caprenin, and ingredients derived using biotechnology.

Based on an evolving need to be responsive to the development of food ingredients resulting from new technologies, FDA wishes to have LSRO/FASEB prepare a comprehensive report on the principles and criteria generally agreed upon by the community of food safety experts for determining when the traditional safety model is appropriate. The agency is also interested in a discussion identifying the principles and criteria to be used to determine the safety of a food ingredient when the traditional safety model is not appropriate. FDA is especially interested in a discussion of how different principles and criteria should be ranked and weighted, interrelationships that should be considered, and any situation where a principle or criterion might be considered determinative without regard to other considerations. It would also be desirable to have a discussion about how the new testing approaches may substitute for more traditional testing.

In framing this discussion, FDA has suggested that the following questions be considered. These questions are not intended as a statement of specific tasks. They are intended to be illustrative and to be used as a basis for stimulating thinking regarding the determination of the safe use of food ingredients.

1. In what cases, if any, are animal feeding studies not necessary to ensure safety? For example: Do such studies need to be conducted for ingredients that also occur naturally in foods at similar or higher concentrations? Is it reasonable and necessary to test food-like substances for toxicity and nutritional influences recognizing the potential for confounding results? If so, how?

2. To what extent can chemical and structural similarity to food ingredients known to be safe obviate the need for animal or human testing?

3. What criteria should be used to determine when a treatment-related effect (including effects from nutritional imbalance or interference) is an adverse effect?

4. Are there criteria that can be used to determine whether an adverse effect observed in a study is relevant to human safety as opposed to an effect that is dependent on study design and has no

relevance to safety under actual use conditions?

5. Under what circumstances should clinical studies in humans supplement or replace studies in laboratory animals? How will use of human data affect the need for safety factors? Which parameters should be measured and what study duration is necessary?

6. Is there an agreed-upon basis for determining the maximum level of an additive to be administered in a test diet above which a study should be presumed unacceptable?

7. Can postmarketing surveillance (such as monitoring of use or monitoring of adverse reaction reports by consumers and physicians) be used to ensure safety? For example, can such surveillance be used without compromising safety to verify exposure estimates or to eliminate the need for specific data prior to marketing, thus reducing the need to use worst-case assumptions in a safety evaluation? If so, how could this be accomplished?

The objective of this review is to make recommendations on the set of circumstances under which the scientific community believes that the use of a safety model that is an alternative to the traditional safety model is justified and will ensure the safety of food ingredients. Such discussions would include: (1) Circumstances prompting the need for new types of studies, (2) circumstances in which traditional studies should not be required or should be modified or their use limited, and (3) the appropriate use of safety factors. FDA also requests a description of the principles and criteria that would be used in the nontraditional or alternative situations and a ranking/weighting of these criteria and principles.

The project is divided into two phases. In the first phase, LSRO/FASEB will solicit input from 40 to 60 members of the food safety community. The nature of this input from each individual will be in the form of a 3- to 5-page "white paper" which will contain expert opinion on issues related to food ingredient safety evaluations. Individuals will be asked to furnish sufficient background material with their white papers to provide a basis for comment on the issues being addressed by LSRO/FASEB in this contract.

A Phase I Expert Panel composed of five members will be convened by LSRO/FASEB. LSRO/FASEB staff will assemble a background document for the Phase I Expert Panel that consists of a compilation of the previously obtained comments from the scientific community. This background document is intended to provide a perspective for

the Phase I Expert Panel in its deliberations; it will not be a preliminary draft of the report to be delivered to FDA in fulfillment of the scope of work for the contract task. Upon approval by the Phase I Expert Panel, the background document will be available on or before April 12, 1996, from LSRO/FASEB (address above). The background document will be on display at LSRO/FASEB and the Dockets Management Branch (addresses above).

In Phase II, the Expert Panel will be expanded to eight members. The Phase II Expert Panel will conduct a comprehensive discussion of the principles and criteria generally agreed upon by the community of food safety experts for determining when the traditional safety model is appropriate. More specifically, based on the deliberations of the Phase II Expert Panel, LSRO/FASEB will organize the scientific concepts of food ingredient safety to yield a set of criteria in a report that the agency could then consider in evaluating the safety of food ingredients. Additionally, based on the discussions of the Phase II Expert Panel, the report will identify a ranking and weighting of such considerations that the scientific community would agree could be used to evaluate whether a new or modified food ingredient should be considered safe.

FDA and LSRO/FASEB are announcing that LSRO/FASEB will hold a public meeting on this topic on May 15, 1996. It is anticipated that the meeting will last 1 day, depending on the number of requests to make oral presentations. Requests to make oral presentations at the open meeting must be submitted in writing and received by April 24, 1996. Participants will be required to submit two copies of the written text of oral presentations of scientific data, information, and views on or before May 10, 1996, to LSRO/FASEB (address above) and two copies to the Dockets Management Branch (address above). The meeting will be held in the Chen Auditorium, Lee Bldg., FASEB (address above).

For individuals not wishing to make an oral presentation, FDA and LSRO/FASEB are also inviting submission in writing of scientific data, information, and views. Two copies of these materials must be submitted on or before May 10, 1996, to both LSRO/FASEB and the Dockets Management Branch (addresses above).

Pursuant to its contract with FDA, LSRO/FASEB will provide the agency with a scientific report on the Phase II review and discussions on or about July 31, 1997.

Dated: February 26, 1996.

William K. Hubbard,

*Associate Commissioner for Policy.*

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## Health Resources and Services Administration

### Emergency Medical Services for Children Demonstration Grants

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

**ACTION:** Notice of availability of funds.

**SUMMARY:** The HRSA in collaboration with the National Highway Traffic Safety Administration (NHTSA) announces that applications will be accepted for fiscal year (FY) 1996 funds for grants authorized under section 1910 of the PHS Act. These discretionary grants will be made to States or accredited schools of medicine to support projects for the expansion and improvement of emergency medical services for children (EMSC). Within the HRSA, EMSC grants are administered by the Maternal and Child Health Bureau (MCHB).

This program announcement is subject to the appropriation of funds. Applicants are advised that this program announcement is a contingency action being taken to assure that should funds become available for this purpose, they can be awarded in a timely fashion consistent with the needs of the program as well as to provide for even distribution of funds throughout the fiscal year. At this time, given a continuing resolution and the absence of FY 1996 appropriations for the EMSC program, the amount of available funding for this specific grant program cannot be estimated.

The NHTSA participated with the MCHB in developing program priorities for the EMSC program for FY 1996. The NHTSA will share the Federal monitoring responsibilities for EMSC awards made during FY 1996 and will continue to provide ongoing technical assistance and consultation in regard to the required collaboration/linkages between applicants and their Highway Safety Offices and Emergency Medical Services Agencies for the State(s). Grantees funded under this program are expected to work collaboratively with the State agency or agencies administering the Maternal and Child Health (MCH) and the Children with Special Health Needs (CSHN) programs under the MCH Services Block Grant, Title V of the Social Security Act (42 U.S.C. 701).