

NOTICES

20053

Vegetable oils  
 Sucrose  
 Biotin  
 Citric acid  
 Lecithins  
 Para-hydroxybenzylisothianate  
 Thiamine  
 Urea  
 Vitamin B<sub>6</sub>  
 Sodium and potassium chlorides

PLANNED SCIENTIFIC LITERATURE REVIEW

Amines (filming)  
 Benzoyl peroxide  
 Borax  
 Brandy  
 Calcium stearate  
 Carbon  
 Char smoke flavor  
 Collagen (avtiane)  
 Cyclohexylamine  
 Enzymes (proteolytic)  
 Ferrocyanide salts  
 Glucono delta lactone  
 Glycerol lactopalmitate  
 Hesperidin complex  
 Lignin  
 Malt syrup  
 Milk powder (whole, enzyme modified)  
 Amino tri (methylene phosphoric acid) sodium salt  
 Bergamot oil  
 Bouillon (vegetable, smoked)  
 Butter fat, enzyme modified w/added butyric acid  
 Candellilla wax  
 Carboxymethyl hydroxyethyl cellulose  
 Chlorophyll  
 Corn mint oil (mentha arvensis oil)  
 Enzymes (bacterial)  
 Ferrous citrate  
 Furcelleran  
 Gluten (corn)  
 Gums (vegetable)  
 Iron citrate  
 Liver fractions  
 Methylpolysilicone  
 Mono and diglycerides (sodium sulfoacetate derivatives)  
 < Morpholine  
 < Nickel  
 < Octadecylamines  
 Oiticia  
 Peptone (pepsin-modified soy bean protein; brewers peptones)  
 Piperazine dihydrochloride  
 Potassium gluconate  
 Ruthin  
 Silver-silver dragees  
 Sodium fluoride  
 Sodium metasilicate  
 Soya fatty acid amine (ethoxylated)  
 Starch (food, modified)  
 Vitamin B complex and syrup  
 Yeasts  
 Pepsin  
 Potassium bromate  
 Potassium phosphates  
 Sausage casings (HCl and cellulose fibers)  
 Sodium chlorite  
 Sodium hypochlorite  
 Sodium zinc metasilicate  
 Stearyl alcohol  
 Wax (shellac)  
 Zein powder

To be considered for inclusion in a Scientific Literature Review, two copies of all relevant safety data, and information shall be submitted to the organization preparing the Review before the listed completion date, and the original and two copies of all such information shall simultaneously be sent to GRAS Review Branch (BF-335), Bureau of Foods, Food and Drug Administration, 200 "C" Street SW., Wash., DC 20204. Imme-

diately upon receipt of any such submission, one copy will be placed on display at the Office of the Hearing Clerk, Food and Drug Administration, Rm. 6-88, 5600 Fishers Lane, Rockville, MD 20852, where it may be reviewed during working hours, Monday through Friday.

If the contractor has not been named, the original and four copies of any such data and information shall be submitted to the GRAS Review Branch (address above), which will distribute two copies to the contractor for the Scientific Literature Review when he is selected. A copy of all such submissions will also immediately be placed on display at the office of the Hearing Clerk, at the above address.

If the estimated date of completion of the Review has passed, copies of any such safety data and information shall be submitted to the Select Committee on GRAS Substances and the GRAS Review Branch as provided by the notice published elsewhere in this issue of the FEDERAL REGISTER, and a copy of any such submission will immediately be placed on display at the office of the Hearing Clerk pursuant to that notice.

Dated: July 19, 1973.

A. M. SCHMIDT,

Commissioner of Food and Drugs.

[FR Doc. 73-15220 Filed 7-25-73; 8:45 am]

SAFETY OF GRAS AND PRIOR-SANCTIONED DIRECT HUMAN FOOD INGREDIENTS

Notice of Opportunity To Present Data Information and Views

The Food and Drug Administration is conducting a study of the safety of direct human food ingredients classified as generally recognized as safe (GRAS) or subject to a prior sanction. As part of this study, information on each such ingredient (or group of ingredients), gathered from literature searches and other sources, is being summarized in a series of written Scientific Literature Reviews by organizations under contract with the Food and Drug Administration. The organizations preparing the Scientific Literature Reviews are responsible for including a summary of the world literature on safety published since January 1, 1920. Opportunity is provided, elsewhere in this issue of the FEDERAL REGISTER, for any interested person to submit unpublished safety data and information on these food ingredients for inclusion in Scientific Literature Reviews now under preparation.

Several Scientific Literature Reviews have now been completed and submitted to the Food and Drug Administration. A list of those completed Reviews appears elsewhere in this issue of the FEDERAL REGISTER, (38 FR), and notice is given of their public availability.

The Food and Drug Administration briefly examines each Scientific Literature Review before accepting it. This brief examination covers only the general quality of the work, to make certain that the major scientific information is in-

cluded in a balanced and complete presentation. The examination is not intended to determine that all pertinent scientific information is included. Notice is therefore hereby given that any interested person who, after study of a Scientific Literature Review, believes that additional pertinent published or unpublished data or information should be included in considering the safety of the ingredient(s) covered in the Scientific Literature Review, may submit ten copies of such written data, information, or views to:

Select Committee on GRAS Substances,  
 Federation of American Societies for Experimental Biology,  
 9650 Rockville Pike,  
 Bethesda, MD 20014

The original of this material and two additional copies shall simultaneously be sent to:

Bureau of Foods,  
 Food and Drug Administration,  
 GRAS Review Branch (BF-335),  
 200 "C" Street, S.W.,  
 Washington, DC 20204.

Immediately upon receipt, one copy of any such submission will be placed on display at the office of the Hearing Clerk, Food and Drug Administration, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, where it may be reviewed during working hours, Monday through Friday.

The Select Committee on GRAS Substances is utilizing the services of special consultants with particular expertise in considering specific issues that arise in the evaluation of these substances. The Select Committee also recognizes that the presentation of oral views with respect to the safety of these substances may be helpful in its work. Therefore, an opportunity will be provided for any interested person to present oral views on the safety of these substances to the Select Committee at a hearing, as part of the evaluation process. Notices providing an opportunity to participate in a hearing, for the presentation of such oral views to the Select Committee, will be published in the FEDERAL REGISTER at the appropriate time.

Following completion of its evaluation, the Select Committee will prepare a report to the Commissioner of Food and Drugs containing its evaluation and recommendations, with respect to the safety of the particular ingredient(s) covered by a Scientific Literature Review. Upon acceptance of the report by the Food and Drug Administration, it will be made available to the public in accordance with the notice on this matter published elsewhere in this issue of the FEDERAL REGISTER. After evaluating this report, the Commissioner will publish in the FEDERAL REGISTER, an appropriate proposal to (1) affirm GRAS status, (2) publish a prior sanction, (3) establish an interim food additive regulation, (4) establish a permanent food additive regulation, or (5) eliminate food use of the ingredient. These proposals will be issued pursuant to the procedural provisions contained in §§ 121.40, 121.41 published in the Fed-

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FEDERAL REGISTER of December 2, 1972 (37 FR 25705), and § 121.2000 published in the FEDERAL REGISTER of May 15, 1973 (38 FR 12737). The Commissioner is proposing elsewhere in this issue of the FEDERAL REGISTER, to establish new §§ 121.104 Substances added directly to human food affirmed as generally recognized as safe (GRAS), 121.105 Substances in food contact surfaces affirmed as generally recognized as safe (GRAS), and 121.106 Substances prohibited from use in food. Thus, each food ingredient will be proposed for inclusion in one of these three new sections, in Subpart D (direct human food additives), in Subpart E (prior sanctions), in Subpart F (indirect human food additives), or in Subpart H (Interim human food additives).

Following publication of any such proposal, all interested persons will have an opportunity to submit written comments on the proposal. Where good cause is shown, the Commissioner may order a public hearing at which an oral presentation of data, information, and views may be made. The final regulation will be final agency action from which appeal lies to the courts.

The Commissioner urges the cooperation of all segments of the public in this important work.

Dated: July 19, 1973.

A. M. SCHMIDT,  
Commissioner of Food and Drugs.

[FR Doc. 73-15221 Filed 7-25-73; 8:45 am]

#### SELECT COMMITTEE ON GRAS SUBSTANCES

##### Request for Nominations

The Food and Drug Administration is conducting a study of direct human food ingredients classified as generally recognized as safe (GRAS) or subject to a prior sanction. The available information relating to the safety of each such ingredient is first being evaluated by a Select Committee on GRAS Substances selected by the Life Sciences Research Office of the Federation of American Societies for Experimental Biology under a contract with the Food and Drug Administration. The Select Committee is considering information on GRAS substances provided by a series of Scientific Literature Reviews based primarily upon a literature survey of material published from 1920 to 1973, by current production and consumption patterns obtained from a recent survey by the National Academy of Sciences, and by additional recent toxicological screening tests on certain of the substances. The Select Committee is presently comprised of the following individuals:

1. Dr. Bert N. Ladu, Jr.,  
Dept. of Pharmacology,  
New York University Medical Center,  
New York University School of Medicine,  
550 1st Ave.,  
New York University Medical Center,

2. Dr. John R. McCoy,  
Professor of Comparative Pathology,  
New Jersey College of Medicine & Dentistry,  
Rutgers Medical School,  
P.O. Box 2100,  
New Brunswick, NJ 08902.
3. Dr. Aaron M. Altschul,  
Dept. of Community Medicine & International Health,  
School of Medicine,  
Georgetown University,  
3750 Reservoir Road, NW.,  
Washington, DC 20007.
4. Dr. Joseph P. Borzelleca,  
Professor of Pharmacology,  
Medical College of Virginia,  
Health Sciences Division,  
Virginia Commonwealth University,  
Richmond, VA 23219.
5. Dr. Sanford A. Miller,  
Dept. of Nutrition and Food Science,  
Rm. E-15-464,  
Massachusetts Institute of Technology,  
Cambridge, MA 02139.
6. Dr. Ralph E. H. Stu,  
Consultant,  
4428 Albermarle St., NW.,  
Washington, DC 20016.
7. Dr. John L. Wood,  
University of Tennessee Medical Units,  
62 S. Dunlap St.,  
Memphis, TN 38103.
8. Dr. George L. Plaa,  
Dept. of Pharmacology,  
University of Montreal,  
Faculty of Medicine,  
Case Postale 6128,  
Montreal 101, Que., Canada.
9. Dr. George W. Irving, Jr., Chairman,  
Research Associate,  
Life Sciences Research Office,  
Federation of American Societies for Experimental Biology,  
9650 Rockville Pike,  
Bethesda, MD 20014.

The curriculum vitae of each member of the Select Committee is available for public review at the office of the Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852.

The Life Sciences Research Office plans to increase the size of the Select Committee working on this project. Accordingly, notice is hereby provided for all interested parties to nominate additional qualified scientists to serve on the Select Committee. Nominations are invited from individuals and from consumer, industry, and professional organizations, and should be sent to:

Dr. C. Jellen Carr,  
Life Sciences Research Office,  
Federation of American Societies for Experimental Biology,  
9650 Rockville Pike,  
Bethesda, MD 20014.

Nominations must state that the person nominated is aware of the nomination, is interested in becoming involved in this effort, and appears to have no conflict of interest. A complete curriculum vitae must be enclosed with each nomination.

Dated: July 19, 1973.

A. M. SCHMIDT,  
Commissioner of Food and Drugs.

[FR Doc. 73-15219 Filed 7-25-73; 8:45 am]

#### STATUS OF REVIEW OF GRAS AND PRIOR-SANCTIONED DIRECT HUMAN FOOD INGREDIENTS

##### Notice of Availability of Information

-Food ingredients that are generally recognized as safe (GRAS), or that were sanctioned through action by the Food and Drug Administration or the United States Department of Agriculture prior to enactment of the Food Additives Amendment of 1958, may be utilized in food without first obtaining approval through a food additive regulation. After enactment of the law, the Food and Drug Administration published a partial list of GRAS and prior-sanctioned ingredients in § 121.101. This list was developed without a thorough scientific review of each ingredient.

In his Consumer Message of October 30, 1969, President Nixon directed the Secretary of Health, Education, and Welfare to initiate a full review of all GRAS ingredients. To implement this mandate, the Food and Drug Administration contracted with the Food Protection Committee of the National Academy of Sciences to survey the entire food industry to determine the national production of all GRAS ingredients and the amount of each such ingredient used in any particular food. The National Academy of Sciences report to the Food and Drug Administration incorporated the results of independent surveys conducted by the United States Department of Agriculture as part of its 1965 Household Food Consumption surveys to determine the sizes of food servings used by consumers, and by the Market Research Corporation of America, to determine how frequently representative consumers eat individual servings of foods in specific food categories. The results of the NAS Survey, describing incorporation of USDA and MRCA data, is now available. The complete Survey report also contains various tabular computer printouts describing the use of GRAS food ingredients in NAS food categories and the total exposure of GRAS food ingredients in human foods.

The Food and Drug Administration also contracted with the Franklin Institute Research Laboratories, The Benjamin Franklin Parkway, Philadelphia, PA 19103, to conduct a search of the world literature since January 1, 1920 on the following 72 GRAS food ingredients that were determined to be a matter of high priority:

Ammoniated glycyrrhizin  
Sodium nitrite  
Sodium nitrate  
Potassium nitrate  
Potassium nitrite  
Saccharin (acid)  
Sodium saccharin  
Calcium saccharin  
Ammonium saccharin  
Potassium bisulfite  
Potassium metabisulfite  
Sodium bisulfite  
Sodium metabisulfite  
Sulfur dioxide  
Oil of mustard