

(sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2A4336) has been filed by Chemie Research and Manufacturing Co., Inc., 160 Concord Dr., P.O. Box 181279, Casselberry, FL 32718-1279. The petition proposes that the food additive regulations be amended to provide for the safe use of a glycerin extract of dried grapefruit seeds and pulp as an antimicrobial agent in the processing of fresh or frozen poultry, fish, or shellfish.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before April 17, 1995, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on display any amendments to, or comments on, the petitioners' environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: March 6, 1995.

**Alan M. Rulis,**

*Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.*

[FR Doc. 95-6428 Filed 3-15-95; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 94N-0136]

### **New Monographs and Revisions of Certain Food Chemicals Codex Monographs; Opportunity for Public Comment**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on pending changes to certain Food Chemicals Codex specifications monographs from the third edition and its four supplements. New monographs and additions, revisions, and corrections to current monographs are being prepared for certain substances used as food ingredients, by the National Academy of Sciences/Institute of Medicine (NAS/IOM) Committee on Food Chemicals Codex (the committee). This material will be published in the fourth edition of the Food Chemicals Codex, which is scheduled for release in March 1996. When the committee completes its review of the comments, the agency will announce the availability of copies of the new and revised monographs in a future issue of the **Federal Register**.

**DATES:** Written comments by April 17, 1995. The committee advises that comments received after this date cannot be considered for the fourth edition but will be considered for later supplements.

**ADDRESSES:** Submit written comments and supporting data and documentation to the NAS/IOM Committee on Food Chemicals Codex, National Academy of Sciences, 2101 Constitution Ave. NW., Washington, DC 20418. Submit written request for copies of the proposed new monographs and/or revisions to current monographs to NAS (address above) or the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Fatima N. Johnson, Committee on Food Chemicals Codex, Food and Nutrition Board, National Academy of Sciences, 2101 Constitution Ave. NW., Washington, DC 20418, 202-334-2580; or

Paul M. Kuznesof, Center for Food Safety and Applied Nutrition (HFS-247), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3009.

**SUPPLEMENTARY INFORMATION:** FDA provides contracts to NAS/IOM to support the preparation of the Food Chemicals Codex, which is a compendium of specifications for substances used as food ingredients. Before any specifications are included in a Food Chemicals Codex publication, public announcement is made in the **Federal Register**.

FDA has previously announced that the committee was considering new

monographs and monograph revisions for inclusion in the fourth edition of the Food Chemicals Codex, which is now being prepared. In addition, notice and opportunity for public comment have been given on policies adopted by the committee for the fourth edition on lead and heavy metals specifications (58 FR 38129, July 15, 1993), and on arsenic specifications (59 FR 11789, March 14, 1994).

The committee will continue to provide the opportunity for public comment on intended changes in monographs by means of **Federal Register** notices before their inclusion in the fourth edition. If notice of changes is not provided, the monographs will be carried into the fourth edition unchanged from the third edition or subsequent supplements, except for minor editorial changes. Therefore, interested parties are invited to review all monographs in the third edition of the Food Chemicals Codex and its four supplements in preparation for their inclusion in the fourth edition. Interested parties should submit all suggestions with supporting documentation to the National Academy of Sciences at the above address.

FDA now gives notice that the committee is soliciting comments and information on certain proposed new monographs and revisions to certain additional current monographs. These new monographs and revisions will be published in the fourth edition of the Food Chemicals Codex. The proposed new monographs and revisions to current monographs may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. Copies of the new monographs and proposed revisions to current monographs may be obtained from NAS or the Dockets Management Branch. Requests for copies should be identified with the docket number found in brackets in the heading of this document, and it should specify the monographs desired.

FDA emphasizes, however, that it will not consider adopting and incorporating any of the committee's new monographs or monograph revisions into FDA regulations without ample opportunity for public comment. If FDA decides to propose the adoption of new monographs and changes that have received final approval of the committee, such opportunity for public comment will be announced in a future issue of the **Federal Register**.

The committee invites comments and suggestions on specifications by all interested parties on the proposed new monographs and revisions of current monographs, that follow:

**I. Proposed New Monographs**

Calcium acid pyrophosphate  
Carbon dioxide  
Dammar gum  
Dried yeast  
Ferrous lactate  
Furcelleran  
Gelatin  
Glycerol ester of gum rosin  
Glycerol ester of partially hydrogenated gum rosin  
Magnesium gluconate  
Maltitol syrup  
Partially hydrolyzed proteins  
Sodium potassium tripolyphosphate  
Whey

**II. Current Monographs to Which the Committee Proposes to Make Revisions**

Acacia gum (description, heavy metals, lead)  
*N*-Acetyl-*L*-methionine (specific rotation)  
Acid hydrolysates of proteins ([formerly Acid hydrolyzed proteins] description, requirements, assay, tests)  
Agar (lead)  
*L*-Alanine (specific rotation)  
Alginate (heavy metals, lead)  
Ammonium alginate (heavy metals, lead)  
Annatto extracts (identification, heavy metals, residual solvent, packaging and storage)  
*L*-Arginine (specific rotation, loss on drying)  
*L*-Arginine monohydrochloride (assay, specific rotation)  
Ascorbic acid (functional use in foods, identification, tests)  
*L*-Asparagine (loss on drying)  
Benzoyl peroxide (heavy metals)  
Butadiene-styrene 50/50 rubber (description, heavy metals, lithium, residual hexane)  
Butadiene-styrene 75/25 rubber (description, heavy metals)  
Calcium alginate (ash, heavy metals, lead)  
Calcium glycerophosphate (heavy metals)  
Calcium lactobionate (numerous changes)  
Calcium pantothenate (heavy metals, tests)  
Calcium silicate (heavy metals, lead)  
Calcium peroxide (heavy metals)  
Calcium pantothenate, racemic (heavy metals)  
Calcium phosphate, dibasic (formula weight, functional use in foods, assay, fluoride, heavy metals, lead)  
Calcium phosphate, monobasic (formula weight, fluoride, heavy metals, lead, labeling)  
Calcium phosphate, tribasic (synonym, functional use in foods, fluoride, heavy metals, lead)  
Canola oil (linolenic acid)  
Carmine (description, assay)  
 $\beta$ -Carotene (description, identification, loss on drying, melting range, solution in chloroform)  
Cholic acid (assay, heavy metals, specific rotation)  
Choline chloride (heavy metals, lead)  
Choline bitartrate (heavy metals, lead)  
Copper gluconate (identification)  
Corn oil (Unhydrogenated) (identification)  
*L*-Cysteine Monohydrochloride (specific rotation)  
*L*-Cystine (loss on drying)  
Desoxycholic acid (assay, heavy metals)  
Dexpantenol (identification)

Dextrose (chloride)  
Dimethylpolysiloxane (identification)  
Enzyme preparations (numerous changes)  
FD & C Blue No. 1 (description, identification, mercury, subsidiary colors)  
FD & C Blue No. 2 (description, identification, subsidiary and isomeric colors)  
FD & C Green No. 3 (description, identification, subsidiary colors)  
FD & C Red No. 3 (description, mercury, uncombined intermediates and products of side reactions)  
FD & C Red No. 40 (mercury)  
FD & C Yellow No. 5 (description, ether extracts, subsidiary colors, uncombined intermediates and products of side reactions)  
FD & C Yellow No. 6 (description, subsidiary colors, total color, uncombined intermediates and products of side reactions)  
Ferric phosphate (lead)  
Ferric pyrophosphate (lead)  
Ferrous gluconate (identification, assay, lead)  
Ferrous fumarate (lead)  
Gellan gum (ash, heavy metals)  
*L*-Glutamic acid (residue on ignition, loss on drying, specific rotation)  
*L*-Glutamic acid hydrochloride (assay)  
*L*-Glutamine (identification, assay, loss on drying)  
Glycerin (identification; assay; acrolein, glucose, and ammonium compounds)  
Glycerol ester of wood rosin (heavy metals, lead)  
Glycerol ester of polymerized rosin (heavy metals, lead)  
Glycerol ester of partially dimerized rosin (heavy metals, lead)  
Glycerol ester of tall oil rosin (heavy metals, lead)  
Glycerol ester of partially hydrogenated wood rosin (heavy metals, lead)  
Glyceryl-lacto esters of fatty acids (name change)  
Glycine (assay, loss on drying)  
Grape skin extract (assay, arsenic, sulfur dioxide, packaging and storage)  
Guar gum (acid-insoluble matter, galactomannans, lead, loss on drying, protein)  
Gum Ghatti (heavy metals, lead)  
High-fructose corn syrup (assay, lead, total solids, labeling)  
*L*-Histidine (specific rotation)  
*L*-Histidine monohydrochloride (assay, loss on drying)  
Hydroxylated lecithin (heavy metals)  
Invert sugar (total solids)  
*L*-Isoleucine (specific rotation)  
Karaya gum (heavy metals, insoluble matter, lead, loss on drying)  
Kelp (heavy metals)  
Lanolin, anhydrous (heavy metals)  
Lecithin (heavy metals)  
*L*-Leucine (loss on drying)  
Limestone, ground (heavy metals, mercury)  
Locust (carob) bean gum (lead)  
*L*-Lysine monohydrochloride (specific rotation, assay)  
Magnesium stearate (assay, heavy metals)  
Magnesium silicate (description, heavy metals)  
Manganese gluconate (numerous changes)

Manganese sulfate (heavy metals)  
Manganese glycerophosphate (identification, assay, heavy metals)  
Manganese hypophosphite (heavy metals)  
Mannitol (identification, assay, heavy metals, melting range, specific rotation)  
Masticatory substances, natural (heavy metals)  
*DL*-Methionine (assay, loss on drying)  
*L*-Methionine (assay, heavy metals specific rotation)  
Methyl ester of rosin, partially hydrogenated (heavy metals)  
Methyl formate (delete monograph from the Food Chemicals Codex)  
Mineral oil, white (sulfur compounds)  
Monoglyceride citrate (description)  
Monopotassium *L*-Glutamate (loss on drying)  
Niacinamide (identification, heavy metals)  
Paraffin, synthetic (heavy metals)  
Pectins (numerous changes)  
Pentaerythritol ester of partially hydrogenated wood rosin (heavy metals)  
Pentaerythritol ester of wood rosin (heavy metals)  
Petroleum wax (synonym, description, identification, functional use in foods, heavy metals, lead, ultraviolet absorbance, packaging and storage)  
Petroleum wax, synthetic (synonym, description, heavy metals, lead, ultraviolet absorbance)  
*DL*-Phenylalanine (loss on drying)  
*L*-Phenylalanine (loss on drying, specific rotation)  
Polyisobutylene (heavy metals)  
Polypropylene glycol (residue on ignition)  
Potassium alginate (ash, heavy metals, lead, loss on drying)  
Potassium chloride (description, assay)  
Potassium gluconate (identification, loss on drying)  
Potassium glycerophosphate (identification)  
*L*-Proline (description, specific rotation)  
Propylene glycol (identification, acidity, heavy metals)  
Pyridoxine hydrochloride (assay, heavy metals)  
Riboflavin 5'-phosphate sodium (assay, free riboflavin, riboflavin diphosphate)  
Riboflavin (description, specific rotation)  
*L*-Serine (specific rotation)  
Sodium acid pyrophosphate (assay, heavy metals, lead)  
Sodium alginate (ash, heavy metals, lead, loss on drying)  
Sodium aluminosilicate (lead)  
Sodium aluminum phosphate, acidic (assay, heavy metals, lead)  
Sodium chloride (heavy metals)  
Sodium erythorbate (heavy metals, lead)  
Sodium gluconate (identification, assay)  
Sodium magnesium aluminosilicate (lead)  
Sodium phosphate, tribasic (description)  
Sodium polyphosphates, glassy (description)  
Sorbitan monostearate (identification, assay)  
Sorbitol (identification, chloride, heavy metals, lead, sulfate)  
Sorbitol solution (identification, chloride, heavy metals, lead, reducing sugars, sulfate)  
Soybean oil (unhydrogenated) (identification)  
Spice oleoresins (heavy metals; oleoresin paprika: additional requirements)  
Sucrose (calculation formula for invert sugar)

Sunflower oil (unhydrogenated) (identification)  
 Talc (description, identification, extractable fluoride)  
 Tannic acid (definition, heavy metals, loss on drying)  
 Terpene resin, natural (heavy metals)  
 Terpene resin, synthetic (heavy metals)  
 Thiamine mononitrate (assay)  
 Thiamine hydrochloride (assay)  
 L-Threonine (specific rotation)  
 DL- $\alpha$ -Tocopherol (lead, heavy metals)  
 d- $\alpha$ -Tocopherol concentrate (description, heavy metals, lead)  
 Tocopherols concentrate, mixed (description, heavy metals, lead)  
 DL- $\alpha$ -Tocopheryl acetate (lead, heavy metals)  
 d- $\alpha$ -Tocopheryl acetate (heavy metals, lead)  
 d- $\alpha$ -Tocopheryl acetate concentrate (description, heavy metals, lead)  
 d- $\alpha$ -Tocopheryl acid succinate (heavy metals, lead)  
 Tragacanth (heavy metals, lead)  
 L-Tryptophan (description, specific rotation)  
 L-Tyrosine (specific rotation)  
 L-Valine (specific rotation)  
 Vitamin B<sub>12</sub> (identification, assay)  
 Vitamin D<sub>2</sub> (identification)  
 Vitamin D<sub>3</sub> (identification)  
 Xanthan gum (ash, heavy metals)  
 Xylitol (lead)  
 Yeast extract (formerly Autolyzed yeast extract] description, requirements, assay, other tests)  
 Zinc gluconate (numerous changes)

Interested persons may, on or before April 17, 1995, submit to NAS (address above) written comments regarding the

monographs listed in this notice. Those wishing to make comments are encouraged to submit supporting data and documentation with their comments. Two copies of any comments are to be submitted. Comments and supporting data or documentation are to be identified with the docket number found in brackets in the heading of this document and should include a statement that it is in response to this **Federal Register** notice. NAS will forward a copy of each comment to the Dockets Management Branch (address above). Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 3, 1995.  
**L. Robert Lake**,  
*Acting Director, Center for Food Safety and Applied Nutrition.*  
 [FR Doc. 95-6529 Filed 3-15-95; 8:45 am]  
**BILLING CODE 4160-01-F**

**[Docket No. 95N-0063]**  
**Dey Laboratories, et al.; Withdrawal of Approval of 14 Abbreviated New Drug Applications**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of 14 abbreviated new drug applications (ANDA's). The holders of the ANDA's notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**EFFECTIVE DATE:** April 17, 1995.

**FOR FURTHER INFORMATION CONTACT:** Carolyn C. Harris, Center for Drug Evaluation and Research (HFD-360), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1038.

**SUPPLEMENTARY INFORMATION:** The holders of the ANDA's listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

ANDA no.	Drug	Applicant
70-805	Metaproterenol Sulfate Inhalation Solution, U.S.P., 5%	Dey Laboratories, 2751 Napa Valley Corporate Dr., Napa, CA 94558.
80-086	Sulfadiazine Tablets, 167 milligrams (mg)	Purepac Pharmaceutical, Co., 200 Elmora Ave., Elizabeth, NJ 07207.
80-120	Isoniazid Tablets, 100 mg	Towne, Paulsen & Co., Inc., 14527 South San Pedro St., Gardena, CA 90248.
80-132	Isoniazid Tablets, U.S.P.	Purepac Pharmaceutical, Co.
80-276	Testosterone Propionate Injection	Elkins-Sinn, Inc., 2 Esterbrook Lane, Cherry Hill, NJ 08003-4099.
80-308	Methyltestosterone Buccal Tablets, 10 mg	Purepac Pharmaceutical, Co.
80-309	Methyltestosterone Tablets, 10 mg	Do.
80-310	Methyltestosterone Tablets, 25 mg	Do.
80-459	Hyrocortisone Emulsion Cream, 1%	Elder Pharmaceuticals, Inc., ICN Plaza, 3300 Highland Ave., Costa Mesa, CA 92626.
80-475	Methyltestosterone Tablets	Purepac Pharmaceuticals, Inc.
80-489	Hydrocortisone Ointment, 0.5%	Altana Inc., 60 Baylis Rd., Melville, NY 11747.
80-581	Pyridoxine Hydrochloride Injection U.S.P., 100 mg/milliliter (mL)	Elkins-Sinn, Inc.
80-797	Chlorpheniramine Maleate Injection, 10 mg/mL and 100 mg/mL	Do.
80-928	Proprantheline Bromide Tablets, 15 mg	Geneva Pharmaceuticals, Inc., 2555 West Midway Blvd., Broomfield, CO 80038-0446.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the ANDA's listed above, and all amendments and supplements thereto, is hereby withdrawn, effective April 17, 1995.

Dated: March 2, 1995.  
**Murray M. Lumpkin**,  
*Deputy Director, Center for Drug Evaluation and Research.*  
 [FR Doc. 95-6426 Filed 3-15-95; 8:45 am]  
**BILLING CODE 4160-01-F**

**Advisory Committee; Notice of Meeting**  
**AGENCY:** Food and Drug Administration, HHS.  
**ACTION:** Notice.

**SUMMARY:** This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which