MAR 15 1976

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March 9, 1976

160.106

No. 17

TO: All Members of PVC/VCM Mailing Lists

Ladies and Gentlemen:

Once again we are writing to bring you up-to-date on regulatory and related activities dealing with vinyl chloride and polyvinyl chloride. For the most part, this report focuses on Food and Drug Administration (FDA) matters but we are also including a reminder regarding the Occupational Safety and Health Administration (OSHA) Standard, and some general information we believe will be of interest.

FDA

Many of you will recall our earlier report that the target date for the final FDA Regulations concerning polyvinyl chloride had been moved up from the last quarter of 1976. As a result of our most recent contacts with FDA personnel, we can now advise that the present target is action "before June 30, 1976." Since the technical review of the various submissions has, we understand, not yet been completed, and because this review is a necessary prerequisite for the development of any sound Regulation, it seems unlikely that final Regulations will be promulgated much before the end of June. Furthermore, we understand that no conclusions have yet been reached regarding the EPA-FDA jurisdictional issue regarding PVC pipe.

As a possible clue to present FDA thinking, we think it may be of significance to note that the Federal Register

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for Friday, March 5, 1976 included two Food Additive Regulations covering applications for polyvinyl chloride plastics (copies enclosed). One Regulation results in an amendment to Section 121.2514 (Resinous and polymeric coatings) which permits use of a new vinyl chloride copolymer; the second establishes a new Section 121.2634 and provides for the use of an ultra filtration membrane based, in part, on a vinyl chloride-acrylonitrile copolymer. These new Regulations are of interest because both preambles refer to the September 3, 1975 proposed rulemaking and reaffirm some of the positions set forth in the proposals.

Thus, the coating Regulation preamble notes that the proposed PVC Regulation would exempt coatings from the prohibition for the use of vinyl chloride homopolymers and copolymers; consequently, the new material was deemed "approvable". Somewhat similarly, the preamble to the ultra filtration membrane Regulation noted the Food and Drug Administration's conclusion that the product was similar to the microporous polymeric filters already regulated in Section 121.2631, products which were described in the September 3 proposal as presenting no problem. In addition, however, this preamble also notes that the vinyl chloride resin used to produce the membranes has a residual VC level of less than 1.5 ppm and states that the subsequent production of the membranes and pre-use treatment results "in a reduction of any remaining vinyl chloride to the point that the Commissioner concludes that the use of the ultra filtration membranes would not reasonably be expected to result in vinyl chloride becoming a component of food."

It seems to us that this latter comment is of particular interest for two reasons. Firstly, it constitutes some recognition that products made with resins containing 1.5 ppm of residual monomer can be processed into final products that meet the statutory criterion of "no reasonable expectation of migration". Secondly, this preamble and the preamble for the coating amendment both reaffirm that PVC products can be used in food contact applications provided there is no reasonable expectation that vinyl chloride will migrate to food. In other words, the Food and Drug Administration has, in effect, reaffirmed in two newly final

Regulations the underlying basis for important parts of its September 3, 1975 proposals, i.e. no reasonable expectation of migration of vinyl chloride to food is a sound basis for permitting the use of PVC plastics.

OSHA

April 1, 1976 is, as many of you are aware, the date on which the OSHA Standard for Vinyl Chloride becomes fully operative. In other words, beginning April 1, 1976 the requirement for the use of respirators when exposure exceeds the permitted levels but does not exceed 25 parts per million will no longer be optional with the employee but will be mandatory. The "rumor mill" indicates that some manufacturers may be requesting a postponement of this effective date, but we have initiated no inquiries in this regard so as to avoid inadvertently prejudicing any individual company action. If any such requests have been made or are anticipated, and those making them wish to inform us, we would appreciate being so advised and will, if requested, notify others in the industry by means of another letter such as this one.

General

Of some general interest is a report on the symposium held jointly by the National Institute of Environmental Health Sciences (NIEHS) and the World Health Organization (WHO), an organ of the United Nations, last week. The symposium was held on March 1-3, 1976 to consider potential health hazards in the rubber and plastics industries. Dr. Dixler of our office attended this symposium and we are enclosing a copy of that portion of his report that relates to vinyl chloride and polyvinyl chloride. We think it is somewhat reassuring to learn that no new health or environmental problems related to vinyl chloride exposure have been reported. However, we are also enclosing a copy of a New York Times article which reports a study now being conducted by the National Center for Disease Control. It concerns a possible link between birth defects in the South Charleston, West Virginia area where a PVC plant has long been located.

* * *

As in the past, we shall continue to follow closely governmental and related activities concerning vinyl chloride and polyvinyl chloride so we can report on them to you promptly.

Cordially yours,

James H. Beckman

Enclosures

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omplish their purpose in the public terest. It does not appear that public articipation in the rulemaking proceed- would make additional relevant in- ation available to the Department.

Accordingly, under the administrative rocedure provisions in 5 U.S.C. 553, it found upon good cause that notice nd other public procedure with respect o the amendments are impracticable nd contrary to the public interest, and ood cause is found for making them ffective less than 30 days after publica- on in the FEDERAL REGISTER.

Done at Washington, D.C., this 2d day f March, 1976.

J. M. HEJL,
Deputy Administrator,
Veterinary Services.

[FR Doc.76-6345 Filed 3-4-76;8:45 am]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

[Docket No. 75F-0289]

PART 121—FOOD ADDITIVES

Subpart C—Food Additives Permitted in Feed and Drinking Water of Animals or for the Treatment of Food-Producing Animals

FORMALDEHYDE

The Food and Drug Administration is amending the food additive regulations in Part 121 (21 CFR Part 121) to provide for the safe use of formaldehyde to improve the handling characteristics of animal fat in combination with certain oilseed meals intended for use as a component of cattle feed; effective March , 1976; objections by April 5, 1976.

Notice was given by publication in the FEDERAL REGISTER of December 17, 1975 (40 FR 58484) that a food additive petition (FAP MF 3638) had been filed by Alta Lipids (USA) Ltd., PO Box 1187, Boise, ID 83701, proposing that Part 121, Subpart C, be amended to provide for the safe use of the additive in the feed f beef and nonlactating dairy cattle.

The Commissioner of Food and Drugs having evaluated the data in the food additive petition and other relevant material, concludes that the regulations should be amended to provide for the safe use of the additive as described below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1))), and under authority delegated to the Commissioner (21 CFR 2.120), Part 121, Subpart C, is amended by adding the following new section:

§ 121.329 Formaldehyde.

The food additive formaldehyde may be safely used in the manufacture of animal feeds in accordance with the following conditions:

(a) The additive is used, or intended for use, to improve the handling characteristics of animal fat in combination with certain oilseed meals by producing therefrom a dry, free-flowing product as follows:

(1) An aqueous blend of soybean and sunflower meals in a ratio of 3:1, respectively, is mixed with animal fat such that the oilseed meals and animal fat are in a ratio of 3:2. The feed ingredients are those defined by the "Official Publication" of the Association of American Feed Control Officials, Inc., 1976 ed., pages 86, 103, and 109.[1]

(2) Formaldehyde (37 percent solution) is added to the mixture at a level of 4 percent of the dry matter weight of the oilseed meals and animal fat. This mixture, upon drying, contains not more than 1 percent formaldehyde and not more than 12 percent moisture.

(b) The dried mixture described in paragraph (a) of this section is used, or intended for use, as a component of dry, nonpelleted feeds for beef and nonlactating dairy cattle.

(c) To assure safe use of the additive, in addition to the other information required by the act, the label and labeling of the dried mixture described in paragraph (a) of this section shall bear:

(1) The name of the additive.

(2) Adequate directions for use providing that feed as consumed is not to contain more than 26 percent of the mixture.

Any person who will be adversely affected by the foregoing order may at any time on or before April 5, 1976, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Six copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this order. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date. This order shall become effective March 5, 1976.

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1)))

Dated: March 1, 1976.

NOTE: Incorporation by reference provisions approved by the Director of the Federal Register, February 5, 1970.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc.76-6331 Filed 3-4-76;8:45 am]

[1] Copies may be obtained from: Ernest A. Epps, Jr., Treasurer, Division of Agricultural Chemistry, P.O. Box 16390-A, Baton Rouge, LA 70803.

[Docket No. 76F-0015]

PART 121—FOOD ADDITIVES

Subpart F—Food Additives Resulting From Contact With Containers or Equipment and Food Additives Otherwise Affecting Food

RESINOUS AND POLYMERIC COATINGS

The Food and Drug Administration is amending the food additive regulations in § 121.2514 *Resinous and polymeric coatings* (21 CFR 121.2514) to provide for the safe use of vinyl chloride-vinylidene chloride-2,3-epoxypropyl methacrylate copolymers as components of coatings intended to contact food; effective March 5, 1976; objections by April 5, 1976.

Notice was given by publication in the FEDERAL REGISTER of May 9, 1975 (40 FR 20337) that a petition (FAP 5B3049) had been filed by Union Carbide Corp., River Rd., Bound Brook, NJ 08805, proposing that § 121.2514 be amended to provide for the safe use of vinyl chloride-vinylidene chloride-2,3-epoxypropyl methacrylate copolymers as components of coatings intended to contact food.

The Commissioner of Food and Drugs issued a notice of proposed rule making published in the FEDERAL REGISTER of September 3, 1975 (40 FR 40529) to restrict the use of vinyl chloride polymers in contact with food. The proposed regulations would prohibit the use of vinyl chloride homopolymers and copolymers in food-contact articles except (1) in coatings, gaskets, cap liners, flexible tubing, and plasticized film or (2) if such use was specifically permitted in Part 121 (21 CFR Part 121).

Since the petitioner is seeking use as a coating, such use is approvable under the proposed rules. This petition is therefore being approved conditionally, subject to change if the final regulation on vinyl chloride polymers establishes conditions for use different from those adopted in this regulation. Any such change will be subject to objection and request for hearing.

The Commissioner, having evaluated data in the petition and other relevant material concludes that § 121.2514 should be amended as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1))) and under authority delegated to the Commissioner (21 CFR 2.120), § 121.2514 (b)(3)(xv) is amended by alphabetically inserting in the list of substances a new item, to read as follows:

§ 121.2514 Resinous and polymeric coatings.

* * * * * *

(b) * * *

(3) * * *

(xv) * *

* * * * * *

Vinyl chloride-vinylidene chloride-2,3-epoxypropyl methacrylate copolymers containing not more than 10 weight percent of total polymer units derived from 2,3-epoxypropyl methacrylate and not more than 0.05 weight percent of unreacted 2,3-epoxypropyl methacrylate monomer based

on polymer solids for use only in coatings for containers intended for contact with foods under conditions A, C, D, E, F, G, or H described in Table 2 of paragraph (d) of this section.

* * * * *

Any person who will be adversely affected by the foregoing order may at any time on or before April 5, 1976, file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Six copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this order. Received objections may be seen in the above office during working hours, Monday through Friday.

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1)))

Dated: February 27, 1976.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.76–6332 Filed 3–4–76;8:45 am]

[Docket No. 75F–0351]

PART 121—FOOD ADDITIVES

Subpart F—Food Additives Resulting From Contact With Containers or Equipment and Food Additives Otherwise Affecting Food

POLYETHYLENE PHTHALATE POLYMERS

The Commissioner of Food and Drugs is amending § 121.2524 *Polyethylene phthalate polymers* (21 CFR 121.2524) to provide for the use of spunbonded polyethylene phthalate nonwoven fabric, effective March 5, 1976; objections by April 5, 1976.

Notice was given by publication in the FEDERAL REGISTER of November 25, 1974 (39 FR 41194), that a petition (FAP 5B3039) had been filed by E. I. duPont de Nemours and Co., 1007 Market St., Wilmington, DE 19898, proposing that the food additive regulations (21 CFR Part 121) be amended to provide for safe use of spunbonded polyester nonwoven fabric consisting of ethylene terephthalate polymer and ethylene terephthlate-isophthalate copolymer as articles or components of articles intended to contact food.

The Commissioner, having evaluated data in the petition and other relevant material, concludes that the food additive regulations should be amended as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1))) and under authority delegated to the Commissioner (21 CFR 2.120), Part 121 is amended in § 121.2524 by revising the introductory text and paragraphs (c) and (d), and by adding new paragraph (i) to read as follows:

§ 121.2524 Polyethylene phthalate polymers.

Polyethylene phthalate polymers identified in this section may be safely used as, or components of plastics (films, articles, or fabric) intended for use in contact with food in accordance with the following prescribed conditions:

* * * * *

(c) (1) Polyethylene phthalate spunbonded nonwoven fabric consists of continuous filaments of ethylene terephthalate polymer and ethylene terephthalate-isophthalate copolymer to which may have been added optional adjuvant substances required in their preparation and finishing.

(2) The ethylene terephthalate-isophthalate copolymer component of the fabric shall not exceed 25 percent by weight. The filaments may be blended with other fibers regulated for the specific use and the spunbonded fabric may be further bonded by application of heat and/or pressure.

(3) The fabric shall be used only in accordance with paragraph (i) of this section.

(d) The quantity of any optional substance employed in the production of polyethylene phthalate plastics does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation further provided. Any substance employed in the production of polyethylene phthalate plastics that is the subject of a regulation in Subpart F of this part conforms with any specification in such regulation.

* * * * *

(i) Polyethylene phthalate fabric, identified in paragraph (c) of this section and conforming with the specifications prescribed in paragraph (i)(1) of this section, is used only as provided in paragraph (i)(2) of this section.

(1) *Specifications.* Chloroform-soluble extractives shall not exceed 0.2 milligram/inch² of food-contact surface when exposed to the following solvents at temperatures and times indicated:

(i) Distilled water at 212° F for 2 hours.

(ii) *n*-Heptane at 150° F for 2 hours.

(iii) 50 percent ethyl alcohol at 120° F for 24 hours.

(2) *Conditions of use.* The plastics are intended for:

(i) Dry food contact.

(ii) Bulk food (excluding alcoholic beverages) repeated use applications, including filtration, at temperatures not exceeding 212° F.

(iii) Filtration of bulk alcoholic beverages, not exceeding 50 percent alcohol by volume, at temperatures not exceeding 120° F.

Any person who will be adversely affected by the foregoing order may at any time on or before April 5, 1976, file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Six copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this order. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date. This order shall become effective March 5, 1976.

Dated: February 27, 1976.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.76–6333 Filed 3–4–76;8:45 am]

[Docket No. 75F–0218]

PART 121—FOOD ADDITIVES

Subpart F—Food Additives Resulting From Contact With Containers or Equipment and Food Additives Otherwise Affecting Food

EMULSIFIERS AND/OR SURFACE-ACTIVE AGENTS

The Commissioner of Food and Drugs is amending the food additive regulations in § 121.2541 *Emulsifiers and/or surface-active agents* (21 CFR 121.2541) to provide for specification change in sodium monoalkylphenoxybenzenedisulfonate and sodium dialkylphenoxybenzenedisulfonate mixtures for use as emulsifiers and/or surface active agents in the manufacture of articles intended to contact food; effective March 5, 1976; objections by April 5, 1976.

Notice was given by publication in the FEDERAL REGISTER of September 17, 1975 (40 FR 42912) that a petition (FAP 5B3088) had been filed by Dow Chemical Co., 2030 Dow Center, Midland, MI 48640, proposing that § 121.2541 be amended to provide for specification changes in sodium monoalkylphenoxybenzenedisulfonate and sodium dialkylphenoxybenzenedisulfonate mixtures intended for use as emulsifiers and/or surface-active agents in the manufacture of articles intended to contact food. The specification change would expand the compound to include alkyl groups in the range of C_8–C_{18} as compared to the currently regulated range of C_8–C_{16}.

The Commissioner, having evaluated data in the petition and other relevant material, concludes that § 121.2541 should be amended as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1)

72 Stat. 1786 (21 U.S.C. 348(c)(1))) and under authority delegated to the Commissioner (21 CFR 2.120), § 121.2541 is amended in paragraph (c) to provide for revised specifications for the additive, to read as follows:

§ 121.2541 Emulsifiers and/or surface active agents.

* * * * *

(c) * * *

List of substances:	Limitations
* * *	* * *
Sodium monoalkylphenoxybenzenedisulfonate and sodium dialkylphenoxybenzenedisulfonate mixtures containing not less than 70 percent of the monoalkylated product where the alkyl group is C_6-C_{16}	

* * * * *

Any person who will be adversely affected by the foregoing order may at any time on or before April 5, 1976, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Six copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this order. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date. This order shall become effective March 5, 1976.

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1)))

Dated: February 27, 1976.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.76-6323 Filed 3-4-76;8:45 am]

[Docket No. 75F-0264]

PART 121—FOOD ADDITIVES

Subpart F—Food Additives Resulting From Contact With Containers or Equipment and Food Additives Otherwise Affecting Food

ULTRA-FILTRATION MEMBRANES

The Commissioner of Food and Drugs is adding § 121.2634 (21 CFR 121.2634) to provide for safe use of ultra-filtration membranes formed from vinyl chloride-acrylonitrile copolymers supported on sheets of paper impregnated with cured phenol-formaldehyde resin in the processing of liquid bulk foods, effective March 5, 1976.

The Commissioner issued, in the FEDERAL REGISTER of November 4, 1974 (39 FR 38907), a proposal dealing with a previously unknown migration problem of acrylonitrile monomer. (The migration problem may be common to many food-contact articles containing acrylonitrile copolymers.) The proposal also acknowledged the absence of toxicological data to establish a definitive "no-effect" level for acrylonitrile monomer. The proposal would define the prior sanctions for acrylonitrile copolymers under a new § 121.2010 (21 CFR 121.2010), and it would establish an interim food additive regulation § 121.4010 (21 CFR 121.4010) for such copolymers to allow their continued use while the questions raised are being resolved by further study. Proposed §§ 121.2010 and 121.4010 provide for a tolerance of 0.3 part per million (ppm) as the maximum amount of acrylonitrile monomer that can migrate from the food-contact article; proposed § 121.4010 requires submission of certain chemical and toxicological data to the Food and Drug Administration. Proposed § 121.4010 is intended to apply to all food additive uses of acrylonitrile copolymers.

The Commissioner, having evaluated the data in a petition (FAP 4B2974) filed by Dorr-Oliver, Inc., 77 Havemeyer Lane, Stamford, CT 06904, notice of which was published in the FEDERAL REGISTER of January 21, 1974 (39 FR 2392), and other relevant material, concludes that the food additive regulations (21 CFR Part 121) should be amended as set forth in § 121.2634 below, to provide for safe use of the ultra-filtration membranes mentioned above. Furthermore, the Commissioner concludes that the copolymers described in § 121.2634 will meet the 0.3 ppm acrylonitrile monomer extractives limitation of proposed § 121.4010 when used within the prescribed restrictions. Upon adoption of proposed § 121.4010, § 121.2634 will be amended to cross-reference the requirements of § 121.4010.

The Commissioner issued a notice of proposed rulemaking, published in the FEDERAL REGISTER of September 3, 1975, to restrict the use of vinyl chloride polymers in contact with food (40 FR 40529). The proposed regulations would prohibit the use of vinyl chloride homopolymers and copolymers in food-contact articles except (1) in coatings, gaskets, cap liners, flexible tubing, and plasticized film or (2) if such use was specifically permitted in Part 121. The proposal would also amend a number of food additive regulations consistent with the proposed restrictions. The Commissioner has concluded that the use of vinyl chloride polymers provided by the new § 121.2634 is similar to that for microporous polymeric filters in § 121.2631 which was described in the preamble of the September 3d proposal as being permissible. Data were presented in the petition that the level of residual vinyl chloride in the resin used to produce the ultra-filtration membranes is less than 1.5 ppm. The subsequent production of the membranes and the pre-use treatment required by the regulation would result in a reduction of any remaining vinyl chloride to the point that the Commissioner concludes that the use of the ultra-filtration membranes would not reasonably be expected to result in vinyl chloride becoming a component of food. This petition is therefore being approved conditionally, subject to change if the final regulation on vinyl chloride polymers establishes conditions for use different from those adopted in this regulation. Any such change will be subject to objection and request for hearing.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 402, 409, 701(a), 52 Stat. 1046-1047 as amended, 1055, 72 Stat. 1784-1788 (21 U.S.C. 321(s), 342, 348, 371(a))) and under authority delegated to the Commissioner (21 CFR 2.120), Part 121 is amended by adding § 121.2634 to Subpart F, to read as follows:

§ 121.2634 Ultra-filtration membranes

Ultra-filtration membranes identified in paragraph (a) of this section may be safely used in the processing of food, under the following prescribed conditions:

(a) The ultra-filtration membrane consists of paper impregnated with cured phenol-formaldeyhyde resin, which is used as a support and is coated with a vinyl chloride-acrylonitrile copolymer.

(b) Any substance employed in the production of ultra-filtration membranes that is the subject of a regulation in this Subpart F of Part 121 conforms with the specifications of such regulation.

(c) Ultra-filtration membranes are used in the physical separation of dissolved or colloidally suspended varying molecular size components of liquids during the commercial processing of bulk quantities of food.

(d) Ultra-filtration membranes shall be maintained in a sanitary manner in accordance with good manufacturing practice so as to prevent potential microbial adulteration of the food.

(e) To assure safe use of the ultra-filtration membranes, the label or labeling shall include adequate directions for a pre-use treatment, consisting of conditioning and washing with a minimum of 8 gallons of potable water prior to their first use in contact with food.

Any person who will be adversely affected by the foregoing order may at any time on or before April 5, 1976, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the

objections in the event that a hearing is held. Six copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this order. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date. This order shall become effective March 5, 1976.

(Secs. 201(s), 402, 409, 701(a), 52 Stat. 1046–1047 as amended, 1055, 72 Stat. 1784–1788 (21 U.S.C. 321(s), 342, 348, 371(a)))

Dated: February 27, 1976.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.76-6323 Filed 3-4-76;8:45 am]

SUBCHAPTER D—DRUGS FOR HUMAN USE

[Docket No. 75N-0325]

PART 310—APPROVED NEW DRUGS THAT REQUIRE CONTINUATION OF LONG-TERM STUDIES, RECORDS, AND REPORTS

Revocation of Listing of Levodopa

The Food and Drug Administration is revoking the listing of levodopa in § 310.304(a) (21 CFR 310.304(a)), which required continuation of long-term studies, records, and reports after marketing approval, effective April 5, 1976. The proposed revocation was published in the FEDERAL REGISTER of November 21, 1975 (40 FR 54252). Interested persons were invited to submit comments on the proposal within 60 days. No comments were received, and the revocation is adopted as proposed.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 505(j), 701(a), 52 Stat. 1055, 76 Stat. 782–783 (21 U.S.C. 355(j), 371(a))) and under authority delegated to the Commissioner (21 CFR 2.120), Part 310 is amended in § 310.304 *Drugs that are subjects of approved new-drug applications and that require special studies, records, and reports* by revoking and reserving paragraph (a).

Effective date. This regulation shall be effective April 5, 1976.

(Secs. 505(j), 701(a), 52 Stat. 1055, 76 Stat. 782–783 (21 U.S.C. 355(j), 371(a)))

Dated: February 27, 1976.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.76-6324 Filed 3-4-76;8:45 am]

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

Authorization To Purchase Controlled Substances for Vessels

On September 29, 1975, the Acting Administrator issued a proposal (40 FR 47514, October 9, 1975) to revise § 1301.28(d) of Title 21 of the Code of Federal Regulations regarding procedures for the acquisition of controlled substances by ocean vessels. That notice invited all interested parties to submit their comments or objections to the proposed revision on or before November 10, 1975. No such comments or objections have been received.

Therefore, under the authority vested in the Attorney General by sections 301 and 501(b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 821 and 871(b)), and delegated to the Administrator of the Drug Enforcement Administration by § 0.100 of Title 28 of the Code of Federal Regulations, the Administrator hereby orders that Title 21 of the Code of Federal Regulations be revised to read as follows:

§ 1301.28 Registration regarding ocean vessels.

* * * * *

(d) If no medical officer is employed by the owner or operator of a vessel, or in the event such medical officer is not accessible and the acquisition of controlled substances is required, the master of the vessel, who shall not be registered under the Act, may purchase controlled substances only with the approval of and upon special order form (HSA-590, Authorization to Purchase Controlled Substances for Vessels, formerly HSM-590) provided by a medical officer of the United States Public Health Service. Upon issuance, a copy of each Form HSA-590 will be immediately submitted by the USPHS facility where issued to the Drug Enforcement Administration Regional Office covering the area in which the facility is located. Blank or presigned Form HSA-590 may not be furnished to ships or shipping companies by USPHS.

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This order shall become effective on March 5, 1976.

PETER B. BENSINGER,
Administrator,
Drug Enforcement Administration.

FEBRUARY 27, 1976.

[FR Doc.76-6442 Filed 3-4-76;8:45 am]

Title 26—Internal Revenue

CHAPTER I—INTERNAL REVENUE SERVICE, DEPARTMENT OF THE TREASURY

SUBCHAPTER A—INCOME TAX

[T.D. 7408]

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Interest Deductions of Mortgagors in Case of Certain Assistance Payments

By a notice of proposed rule making appearing in the FEDERAL REGISTER for Wednesday, June 18, 1975 (40 FR 25679), an amendment to the Income Tax Regulations (26 CFR Part 1) under section 163 of the Internal Revenue Code of 1954 (relating to the deduction for interest) was proposed to clarify the income tax effects of assistance payments made by the Department of Housing and Urban Development under section 235 of the National Housing Act (12 U.S.C. 1715z), as amended. After consideration of all such relevant matter as was presented by interested persons regarding the rules proposed, the amendment of the regulations as proposed is adopted by this document without change.

Section 235 of the National Housing Act provides that, if a homeowner and his mortgage satisfy certain specified requirements, the Department of Housing and Urban Development may make assistance payments to the mortgagee. These payments are to be in an amount up to the lesser of (1) the excess of the monthly payment for principal, interest, taxes, insurance and mortgage insurance premium over 20 percent of the mortgagor's income, or (2) the difference between the amount of the monthly payment for principal, interest, and mortgage insurance premium and the amount which would be due for principal and interest if the mortgage bore interest at the rate of one percent.

The Congressional committee reports relating to section 235 indicate that the intent of Congress in enacting the section was to "authorize a new program of interest subsidies to low and moderate income families to purchase new or existing homes which they could not otherwise afford."

Accordingly, the amendment to the regulations provides that a taxpayer is not entitled to deduct interest on an indebtedness to the extent of assistance payments that are made with respect to the indebtedness by the Department of Housing and Urban Development. No portion of the assistance payments would reduce other deductions, such as the deduction for taxes. The amendment is effective for taxable years beginning after December 31, 1974.

Rev. Rul. 75-271, 1975§28 I.R.B. 8, states that payments to a mortgagee under section 235 are not includible in the gross income of the mortgagor.

Adoption of amendment to the regulation. On Wednesday, June 18, 1975, notice of proposed rulemaking with respect to the amendment of the Income Tax Regulations (26 CFR Part 1) under section 163 of the Internal Revenue Code of 1954, in order to clarify the income tax effects of assistance payments made by the Department of Housing and Urban Development under section 235 of the National Housing Act (12 U.S.C. 1715z), as amended, was published in the FEDERAL REGISTER (40 FR 25679). After consideration of all such relevant matter as was presented by interested persons regarding the rules proposed, the amendment of the regulations is hereby adopted as proposed.

(Sec. 7805, Internal Revenue Code of 1954 (68A Stat. 917; 26 U.S.C. 7805))

DONALD C. ALEXANDER,
Commissioner of Internal Revenue.

Approved: March 1, 1976.

CHARLES M. WALKER,
Assistant Secretary of the Treasury.