Final BPT Development Document. Long-term average BOD5 final effluent mass loading were calculated by multiplying the final effluent BOD5 concentrations by the flows.

The resulting BOD5 limitations for the three options are presented below:

FINAL EFFLUENT BOD5 LEVELS

BPT option	Flow (1,000 gallon per ton)	SSL recovery (percent)	Long-term average BOD5 effluent levels (pounds per ton)
1	66.0	95	33.1
2	72.4	92.1	35.6
3	84.5	92.1	38.5

Option 1 represents the methodology used in the March 12, 1980 proposal; however, data for the mill which was not producing acetate grade pulp have been excluded. Effluent limitations for Option 2 are based on BOD5 secondary waste load data corresponding the 92.1 percent SSL recovery rate from a representative mill producing acetate grade dissolving sulfite pulp. The flow for this option, 72.4 kgal/ton, is based on the 66 kgal/ton flow used in promulgating BPT for cellophane grade production but adjusted for yield differences between cellophane and acetate grade pulp production. Option 3 represents the actual flow and SSL recovery conditions at a representative mill.

EPA's preferred option is Option 2. Because this option is based on an actual SSL recovery rate for a representative mill and a flow rate adjusted for the difference in acetate and cellophane yields, the Agency believes that this option is most consistent with the BPT effluent limitations already in effect for the other segments of the dissolving sulfite pulp subcategory and for the entire industry.

After application of variability factors, the resulting maximum 30-day and maximum day effluent limitations corresponding to Option 2 are 63.4 and 121.8 lb/ton, respectively.

Upon compliance with Option 2 effluent limitations, the Agency estimates that total conventional pollutant removals will be 73.0 million kg/yr (160.8 million lbs/yr) of BOD5. These represent removals of 93 percent BOD5 from the raw waste levels of these pollutants.

EPA anticipates that the two dissolving sulfite pulp mills currently manufacturing acetate grade pulp will incure compliance costs. EPA expects that both mill would spend a total of approximately $13.5 million (capital cost) and $6.6 million (total annual cost) in upgrading their existing treatment systems to attain the option 2 BOD5 effluent levels (1978 dollars).

IV. Solicitation of Comments

The Agency is making available all information and comments received after the March 1980 proposal and has also placed in the record all analyses related to the three regulatory options now being considered as the basis for BPT effluent limitations, including model mill cost estimates corresponding to each regulatory option and mill-specific compliance cost estimates. After evaluating comments received on this notice, the Agency will finalize the economic impact analysis done previously, taking into account the revised costs and using the same methodology.

EPA invites and encourages public participation in response to this notice of availability. Of particular interest to EPA are information and data relating to the following:

1. The appropriateness of the BPT TSS effluent limitations for acetate grade production in the dissolving sulfite pulp subcategory in light of the potential revision in the flow basis of the BPT BOD5 effluent limitations.

2. The reasonableness of EPA's mill-specific compliance cost estimates. EPA is interested in receiving information on the anticipated cost of compliance with the BPT BOD5 effluent limitations taking into account current BOD5 discharge levels at the two affected mills.

Dated: August 28, 1985.

Henry L. Longest II,

Acting Assistant Administrator for Water.

[FR Doc. 85-21294 Filed 9-5-85; 8:45 am]

BILLING CODE 6560-50-M

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40 CFR Part 799

[OPTS-42070; T5H-FRL 2881-5]

Benzyl Butyl Phthalate; Proposed Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to require certain environmental fate and effects tests for benzyl butyl phthalate (CAS No. 85-68-7). These are acute and chronic toxicity tests in freshwater and saltwater organisms, bioconcentration testing in the Eastern oyster, and testing for the fate of benzyl butyl phthalate in undisturbed sediments. Interested persons are invited to comment.

DATE: Comments must be submitted by November 5, 1985.

ADDRESS: Submit written comments, identified by the document control number OPTS-42070, in triplicate to: TSCA Public Information Office (TS-783), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Room E-108, 401 M Street SW., Washington, D.C. 20460

Include the document control number (OPTS-42070) on all submissions.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Room E-543, 401 M Street SW., Washington, D.C. 20460. Toll Free: (800-424-9065). In Washington, D.C.: (554-1404). Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION: The Interagency Testing Committee (ITC), in its Seventh Report, designated benzyl butyl phthalate (BBP) for priority consideration of environmental and health effects testing. In the **Federal Register** of October 30, 1981 (46 FR 53775), EPA published a preliminary decision not to propose a section 4(a) rule under the Toxic Substances Control Act (TSCA) to require environmental or health effects testing of BBP. This decision was based on the Agency's acceptance of a comprehensive testing proposal for phthalate esters and BBP from the Chemical Manufacturers Association (CMA) on behalf of the Phthalate Esters Program Panel (PEPP), and upon the actions of the National Toxicology Program (NTP) to perform additional studies in oncogenicity and reproductive effects of BBP. In a follow-up notice, published in the **Federal Register** of January 5, 1982 (47 FR 335), in response to public comment, EPA confirmed its decision not to propose rulemaking for BBP. In August 1984 a suit brought against EPA resulted in the ruling that negotiated testing agreements are not a legally adequate substitute for test rules in response to the designation of chemicals by the ITC (*NRDC v. EPA*, 595 F. Supp. 1255 (S.D.N.Y. 1984)). Thus, EPA must now either initiate rulemaking or publish a decision not to do so. EPA is therefore issuing a proposed rule to obtain additional environmental fate and effects testing of benzyl butyl phthalate.

I. Introduction

A. ITC Recommendation

Section 4(e) of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.* 15 U.S.C. 2601 *et seq.*) established an Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals to be considered for the promulgation of test rules under section 4(a) of the Act.

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Conditionally Approved Products (AMA Guideline Formulations)

The products listed below have received conditional approval under the terms of the July 13, 1979 notice.

1. NDA 6-071; Berocca PN containing vitamin A (palmitate) 3,300 International Units (I.U.)/vial, vitamin D (ergocalciferol) 200 U.S.P. units/milliliter (mL), vitamin E (dl-alpha tocopherol) 10 U.S.P. units/mL, vitamin C (ascorbic acid) 100 milligrams (mg)/mL, folic acid 400 micrograms (mcg)/mL, niacin (niacinamide) 40 mg/mL, vitamin B_2 (riboflavin 5'-phosphate sodium) 3.6 mg/mL, vitamin B_1 (thiamine hydrochloride) 3 mg/mL, vitamin B_6 (pyridoxine hydrochloride) 4 mg/mL, vitamin B_{12} (cyanocobalamin) 5 mcg/mL, pantothenic acid (dexpanthenol) 15 mg/mL, and d-biotin 60 mcg/mL; Roche Laboratories, Division of Hoffmann La-Roche Inc., Roche Park, Nutley, NJ 07110.

2. NDA 6-071; Berocca-WS containing vitamin C (ascorbic acid) 100 mg/mL, folic acid 400 mcg/mL, niacin (niacinamide) 40 mg/mL, vitamin B_2 (riboflavin 5'-phosphate sodium) 3.6 mg/mL, vitamin B_1 (thiamine hydrochloride) 3 mg/mL, vitamin B_6 (pyridoxine hydrochloride) 4.0 mg/mL, vitamin B_{12} (cyanocobalamin) 5 mcg/mL, pantothenic acid (d-panthenol) 15 mg/mL, and d-biotin 60 mcg/mL; Roche Laboratories, Inc.

3. NDA 8-809; MVI-12 containing vitamin A (retinol) 3,300 I.U./vial, vitamin D (ergocalciferol) 200 I.U./vial, vitamin E (dl-alpha tocopherol acetate) 10 I.U./vial, vitamin C (ascorbic acid) 100 mg/vial, folic acid 400 mcg/vial, niacin (niacinamide) 40 mg/vial, vitamin B_2 (riboflavin 5'-phosphate sodium) 3.6 mg/vial, vitamin B_1 (thiamine hydrochloride) 3.0 mg/vial, vitamin B_6 (pyridoxine hydrochloride) 4.0 mg/vial, vitamin B_{12} (cyanocobalamin) 5 mcg/vial, pantothenic acid (d-panthenolalcohol) 15 mg/vial, biotin 60 mcg/vial; USV Laboratories Division, USV Pharmaceuticals, Tuckahoe, NY 10707.

4. NDA 18-223; Multivitamin Additive containing vitamin A 3,300 I.U./5 mL, vitamin D 200 I.U./5 mL, vitamin E 10 I.U./5 mL, vitamin C (ascorbic acid) 100 mg/5 mL, folic acid 400 mcg/5 mL, niacin (niacinamide) 40 mg/5 mL, vitamin B_2 (riboflavin 5'-phosphate sodium) 3.6 mg/5 mL, vitamin B_1 (thiamine hydrochloride) 3.0 mg/5 mL, vitamin B_6 (pyridoxine hydrochloride) 4.0 mg/5 mL, vitamin B_{12} (cyanocobalamin) 5 mcg/5 mL, pantothenic acid (pantothenyl alcohol) 15 mg/5 mL, d-biotin 60 mcg/5 mL; Abbott Labs, North Chicago, IL 60064.

5. NDA 18-439; MVC Plus containing vitamin A (retinol) 3,300 I.U./10 mL, vitamin D (ergocalciferol) 200 I.U./10 mL, vitamin E (dl-alpha tocopherol acetate) 10 I.U./10 mL, vitamin C (ascorbic acid) 100 mg/10 mL, folic acid 400 mcg/10 mL, niacin (niacinamide) 40 mg/10 mL, vitamin B_2 (riboflavin 5' phosphate sodium) 3.6 mg/10 mL, vitamin B_1 (thiamine hydrochloride) 3 mg/10 mL, vitamin B_6 (pyridoxine hydrochloride) 4 mg/10 mL, vitamin B_{12} 5 mcg/10 mL, pantothenic acid (dexpanthenol) 15 mg/10 mL, biotin 60 mcg/10 mL; Ascot Hospital Pharmaceuticals, Inc., Skokie, IL 60076.

6. NDA 18-440; M.V.C. 9+3 containing vitamin A (retinol) 3,300 I.U./5 mL, vitamin D (ergocalciferol) 200 I.U./5 mL, vitamin E (dl-alpha tocopherol acetate) 10 I.U./5 mL, vitamin C (ascorbic acid) 100 mg/5 mL, folic acid 400 mcg/5 mL, niacin (niacinamide) 40.0 mg/5 mL, vitamin B_2 (riboflavin-5'-phosphate) 3.6 mg/5 mL, vitamin B_1 (thiamine hydrochloride) 3.0 mg/5 mL, vitamin B_6 (pyridoxine hydrochloride) 4.0 mg/5 mL, vitamin B_{12} (cyanocobalamin) 5 mcg/5 mL, pantothenic acid (dexpanthenol) 15.0 mg/5 mL, and biotin 60 mcg/5 mL; Lypho Med. Inc., Chicago, IL 60651.

7. NDA 18-920; M.V.I. Pediatric (lyophilized) each vial containing vitamin A (retinol) 2,300 U.S.P. units/vial, vitamin D (ergocalciferol) 400 U.S.P. units/vial, vitamin E (dl-alpha tocopherol acetate) 7 U.S.P. units/vial, vitamin C (ascorbic acid) 80 mg/vial, folic acid 140 mcg/vial, niacin (niacinamide) 17.0 mg/vial, vitamin B_2 (riboflavin-5'-phosphate sodium) 1.4 mg/vial, vitamin B_1 (thiamine hydrochloride) 1.2 mg/vial, vitamin B_6 (pyridoxine hydrochloride) 1.0 mg/vial, vitamin B_{12} (cyanocobalamin) 1 mcg/vial, dexpanthenol (d-pantothenyl alcohol) 5.0 mg/vial, biotin 20 mcg/vial, vitamin K_1 (phytonadione) 200 mcg/vial; Armour Pharmaceutical Co., P.O. Box 511, Kankakee, IL 60901.

8. NDA 18-933; M.V.I.-12 Lyophilized each vial containing vitamin A (retinol) 3,300 U.S.P. units, vitamin D (ergocalciferol) 200 units, vitamin E (dl-alpha tocopherol acetate) 10 U.S.P. units, vitamin C (ascorbic acid) 100 mg, folic acid 400 mcg, niacin (niacinamide) 40 mg, vitamin B_2 (riboflavin-5'-phosphate sodium) 3.6 mg, vitamin B_1 (thiamine) 3.0 mg, vitamin B_6 (pyridoxine) 4.0 mg, vitamin B_{12} (cyanocobalamin) 5 mcg, dexpanthenol (d-pantothenyl alcohol) 15.0 mg, biotin 60 mcg; Armour Pharmaceutical Co.

The Director of the Center for Drugs and Biologics has considered the results from the clinical trials on the recommended AMA formulations, and other available material, and has determined that except for the pediatric parenteral formulation, the 1975 AMA guideline formulations are effective multivitamin preparations. However, the Director recognizes that as these products are used and evaluated in an ever increasing number of patients with a variety of disease conditions, future adjustments to the formulations may be necessary.

The temporary exemption announced in the December 14, 1972 notice as it pertains to any drug product of composition given above is hereby revoked. The drugs listed above are regarded as new drugs (21 U.S.C. 321(p)). A fully approved new drug application is now required for marketing them (except for M.V.I. Pediatric, as explained below). A supplemental new drug application is required for the products listed above (except for M.V.I. Pediatric) to revise their labeling to update the previous "conditionally approved" new drug applications providing for them.

In light of recent events involving reports of adverse effects associated with the use of a particular single entity parenteral vitamin E product in premature and low-birth-weight infants, the Director has determined that further evaluation of pediatric parenteral multivitamin formulations which contain vitamin E is required. (At the current time, it is unknown whether the adverse effects associated with the single entity product are related to the relatively large dosage of vitamin E administered, to the solubilizer in the product formulation, or to some other factor.) A future Federal Register notice will address the agency's conclusions on these products. Until that time, pediatric multivitamin products may be marketed only under the terms and conditions of the July 13, 1979 Federal Register notice (41 FR 40933).

Products Lacking Substantial Evidence of Effectiveness

The three products listed below were included in the initial DESI notice of July 27, 1972 (37 FR 15027). The sponsors of these products provided for a reformulated preparation in accord with the AMA guidelines as stated in the July 13, 1979 notice (44 FR 40933), and received conditional approval. Under the terms of that notice, the original products could remain on the market pending evaluation of the AMA guideline formulations. Insofar as the guideline formulations have now been found to be effective, the original formulations are now classified as lacking substantial evidence of effectiveness, their paragraph XIV

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exemption is hereby revoked, and the Director proposes to withdraw approval of the following parts of the new drug applications, that provide for them:

1. NDA 6-071; those parts that provide for Berocca C and Berocca C-500 Injectable both containing thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, dexpanthenol, d-biotin, and ascorbic acid; Roche Laboratories, Inc.

2. NDA 8-809; those parts that provide for M.V.I. Injectable containing ascorbic acid, vitamin A, ergocalciferol, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, dexpanthenol, and dl-alpha tocopherol acetate; USV Pharmaceuticals.

In addition to the holder of the new drug applications named above, this notice applies to any person who manufactures or distributes a drug product that is not the subject of an approved new drug application and that is identical to a drug product named above. It may also be applicable, under 21 CFR 310.6, to a related or similar drug product that is not the subject of an approved new drug application. It is the responsibility of every drug manufacturer or distributor to review this notice to determine whether it covers any drug product that the person manufactures or distributes. Any person may request an opinion of the applicability of this notice to a specifc drug product by writing to the Division of Drug Labeling Compliance (address given above).

Conditions for Approval and Continued Marketing of Formulations Evaluated as Effective

FDA has reviewed all available evidence and concludes that the parenteral multivitamin drug products formulated as listed below are effective for the applicable indication listed in the labeling conditions below.

Conditions for Approval and Marketing. FDA is prepared to approve abbreviated new drug applications and supplements to the conditionally approved new drug applications listed above (except for M.V.I. Pediatric) under conditions described herein.

1. *Form of drug.*

(a) *Intravenous Multivitamin Preparations.* The preparation is an aqueous solution or lyophilized powder suitable for reconstitution and/or secondary dilution prior to intravenous infusion, and contains the specified amounts of the following individual vitamins, either as the moiety listed below or as the chemically equivalent salt or ester.

(i) *Adult formulation* (intended for ages 11 and older)

Ingredient	Amount per unit dose
Fat soluble vitamins	
A (retinol)	3300 I.U.
D (ergocalciferol or cholecalciferol)	200 I.U.
E (alpha-tocopherol)	10 I.U.
Water soluble vitamins	
C (ascorbic acid)	100 mg.
Folic acid	400 mcg.
Niacin	40 mg.
B_2 (riboflavin)	3.6 mg.
B_1 (thiamine)	3.0 mg.
B_6 (pyridoxine)	4.0 mg.
B_{12} (cyanocobalamin)	5.0 mcg.
Pantothenic acid	15.0 mg.
Biotin	60.0 mcg.

(b) *Intramuscular Multivitamin Preparations.* The preparation is a sterile solution suitable for intramuscular injection.

(i) *Adult formulation.* The vitamin composition of the adult intramuscular formulation shall be that of the adult preparation (listed above) *without* the fat soluble vitamins.

2. *Labeling Conditions.*

(a) The label bears the statement "Caution: Federal Law prohibits dispensing without prescription."

(b) The drug is labeled to comply with all requirements of the act and regulations, and the labeling bears adequate information for safe and effective use of the drug. The indication is as follows:

(i) *Intravenous Multivitamin Preparations.*

(a) *Adult.* This formulation is indicated as daily multivitamin maintenance dosage for adults and children age 11 and above receiving parenteral nutrition. It is also indicated in other situations where administration by the intravenous route is required. Such situations include surgery, excessive burns, fractures and other trauma, severe infectious diseases, and comatose states, which may provoke a "stress" situation with profound alterations in the body's metabolic demands and consequent tissue depletion of nutrients.

The physician should not await the development of clinical signs of vitamin deficiency before initiating vitamin therapy. The use of a multivitamin product obviates the need to speculate on the status of individual vitamin nutriture.

This product (administered in intravenous fluids under proper dilution) contributes intake of these necessary vitamins, except vitamin K, toward maintaining the body's normal resistance and repair processes.

Patients with multiple vitamin deficiencies or with markedly increased requirements may be given multiples of the daily dosage for two or more days as indicated by the clinical status. This product does not contain vitamin K, which may have to be administered separately. Clinical testing indicates that some patients do not maintain adequate levels of certain vitamins when this formulation in recommended amounts is the sole source of vitamins. No vitamin deficiencies were clinically evident, but blood levels of vitamin A, C, D, and folic acid declined in a number of subjects who received this formulation as the only vitamin source for 4 to 6 months. Therefore, in patients for whom total parenteral nutrition will be continued for long periods of time, these vitamins should be monitored. If deficiencies appear to be developing, multiples of the formulation (1.5 to 3 times) may be needed for a period of time. When multiples of the formulation are used for more than a few weeks, vitamins A and D should be monitored occasionally to be certain that an excess accumulation of these vitamins is not occurring.

(ii) *Intramuscular Multivitamin Preparations.*

(a) *Adult.* This product is indicated for adults and children 11 years of age or older for conditions in which (1) intake or absorption of the water-soluble vitamins is inadequate and oral intake must be supplemented; or (2) there is a known or suspected serious depletion of the water-soluble vitamins and immediate treatment by the intramuscular route is advisable.

Conditions which may require parenteral administration of water-soluble vitamins may include disorders which can affect oral intake, gastrointestinal absorption, or utilization, such as: comatose states, persistent vomiting, prolonged fever, severe infectious diseases, major surgery, extensive burns, fractures and other traumas, chronic alcoholism, diarrhea, achlorhydria, or liver disease.

The physician should not await the development of clinical signs of vitamin deficiency before initiating therapy as there are few specific or pathognomonic signs of early vitamin deficiencies.

(c) CONTRAINDICATIONS: Known hypersensitivity to any of the vitamins in this product or a pre-existing hypervitaminosis.

3. *Marketing Status.* (a) Marketing of the drug products that are now the subjects of conditionally approved new drug applications (except for M.V.I. Pediatric) may be continued provided that on or before November 16, 1984 the holder of the application submits (i) a supplement for revised labeling as needed to be in accord with the labeling conditions described in this notice, and complete container labeling if current container labeling has not been submitted, and (ii) a supplement to provide updating information with respect to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls) of new drug application form FD-356H (21 CFR 314.1(c)). FDA will evaluate the submitted material and, if adequate, will grant full approval to the conditionally approved new drug applications.

(b) Approval of an abbreviated new drug application (21 CFR 314.2) containing full information with respect to items 6 (components), 7 (composition), and 8 (methods, facilities,

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and controls) of new drug application form FD-356H (21 CFR 314.1(c)) must be obtained before marketing such products. The bioavailability regulations (21 CFR 320.21) require any person submitting a full or abbreviated new drug application after July 7, 1977, to include either evidence demonstrating the in vivo bioavailability of the formulation or information to permit waiver of the requirement. The bioavailability requirements are waived under 21 CFR 320.22(b)(1) for intravenous products formulated described in this notice (see section 1(a) *Form of Drug*). Marketing the drug products before approval of a new drug application will subject the products, and those persons who caused the products to be marketed, to regulatory action.

(c) Marketing of M.V.I. Pediatric may be continued under the terms and conditions of the July 13, 1979 Federal Register notice (41 FR 40933).

Notice of Opportunity for Hearing

On the basis of all the data and information available to him, the Director of the Center for Drugs and Biologics is unaware of any adequate and well-controlled clinical investigation, conducted by experts qualified by scientific training and experience, meeting the requirements of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and 21 CFR 314.111(a)(5) and 300.50, and demonstrating the effectiveness of the parenteral multivitamin formulations listed above under *"Products Lacking Substantial Evidence of Effectiveness."*

Therefore, notice is given to the holders of the new drug applications and to all other interested persons, that the Director of the Center for Drugs and Biologics proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), withdrawing approval of those parts of the new drug applications and all amendments and supplements thereto providing for the formulations classified as lacking substantial evidence of effectiveness on the ground that new information before him with respect to the drug products, evaluated together with the evidence available to him when the applications were approved, shows there is a lack of substantial evidence that these formulations will have the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling. If no hearing is requested, then those parts of the new drug applications that pertain to the formulations evaluated as lacking substantial evidence of effectiveness (part of NDA 6-071 providing for Berocca C and Berocca C-500; part of NDA 8-809 providing for M.V.I. Injectable) will be considered withdrawn and no further order will issue.

This notice of opportunity for hearing encompasses all issues relating to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in 21 CFR 310.6), e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act (21 U.S.C. 321(p)) or because it is exempt from part or all of the new drug provisions of the act under the exemption for products marketed before June 25, 1938, in section 201(p) of the act, or under section 107(c) of the Drug Amendments of 1962, or for any other reason.

In accordance with section 505 of the act (21 U.S.C. 355) and the regulations promulgated under it (21 CFR Parts 310 and 314), the applicants and all other persons who manufacture or distribute a drug product that is identical, related, or similar to the drug products named above (21 CFR 310.6), and not the subject of an approved new drug application, are hereby given an opportunity for a hearing to show why approval of those parts of the new drug applications providing for the formulations evaluated as lacking substantial evidence of effectiveness should not be withdrawn, and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products named above and of all identical, related, or similar drug products not the subject of an approved new drug application.

The applicant or any other person subject to this notice under 21 CFR 310.6 who decide to seek a hearing, shall file (1) on or before December 17, 1984 a written notice of appearance and request for hearing, and (2) on or before November 16, 1984 the data, information, and analyses relied on to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this proposal to withdraw approval. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and a granting or denial of a hearing are contained in 21 CFR 314.200.

The failure of the applicants or any other person subject to this notice under 21 CFR 310.6 to file a timely written notice of appearance and request for hearing as required by 21 CFR 314.200 constitutes an election by the person not to make use of the opportunity for a hearing concerning the action proposed, and a waiver of any contentions concerning the legal status of the relevant drug product. Any such drug product, the composition of which has been evaluated in this notice as lacking substantial evidence of effectiveness, may not thereafter lawfully be marketed, and the Food and Drug Administration will initiate appropriate regulatory action to remove such a drug product from the market. Any new drug product marketed without an approved new drug application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the affected parts of the applications, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions pursuant to this notice are to be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-1053 as amended (21 U.S.C. 352, 355)), and under the authority delegated to the Director of the Center for Drugs and Biologics (21 CFR 5.70 and 5.82).

Dated: September 12, 1984.

Harry M. Meyer, Jr.,

Director, Center for Drugs and Biologics.

[FR Doc. 84-24000 Filed 9-14-84; 8:45 am]

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