Application No.	Drug	Applicant
ANDA 87–107	Heparin Sodium Injection USP, 10,000 units/mL (syringe).	SoloPak Laboratories
ANDA 87–109	Nitroglycerin Extended-Release Capsules, 9 mg	KV Pharmaceutical Co.
ANDA 87–310	Hydroxyzine Hydrochloride Injection USP, 50 mg/mL.	SoloPak Laboratories
ANDA 87–344	Isosorbide Dinitrate Extended-release Capsules, 40 mg.	Inwood Laboratories, Inc., 909 Third Ave., New York, NY 10022–4731.
ANDA 87–363	Heparin Sodium Injection USP, 10,000 units/0.5 mL (syringe).	SoloPak Laboratories
ANDA 87–395	Heparin Sodium Injection USP, 5,000 units/0.5 mL (syringe).	Do.
ANDA 87–551	Cyanocobalamin Injection USP, 1,000 micrograms/mL (syringe).	Do.
ANDA 87–596	Hydroxyzine Hydrochloride Injection USP, 50 mg/mL and 100 mg/mL.	Do.
ANDA 87–903	Heparin Lock Flush Solution USP, 10 units/mL (syringe).	Do.
ANDA 87–905	Heparin Lock Flush Solution USP, 100 units/mL (syringe).	Do.
ANDA 88–120	Hydroxyzine Hydrochloride Tablets USP, 10 mg	Purepac Pharmaceutical Co.
ANDA 88–121	Hydroxyzine Hydrochloride Tablets USP, 25 mg	Do.
ANDA 88–122	Hydroxyzine Hydrochloride Tablets USP, 50 mg	Do.
ANDA 88–139	Chlorthalidone Tablets USP, 25 mg	Do.
ANDA 88–177	Hydralazine Hydrochloride Tablets, 25 mg	Do.
ANDA 88–520	Phenytoin Sodium Injection USP, 50 mg/mL (syringe).	SoloPak Laboratories
ANDA 88–532	Procainamide Hydrochloride Injection USP, 500 mg/mL (syringe).	Do.
ANDA 89–094	Trimethobenzamide Hydrochloride Injection USP, 100 mg/mL (syringe).	Do.

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of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective December 29, 1997.

Dated: November 17, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–31214 Filed 11–26–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0451]

Microbial Safety of Produce; Grassroots and International Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing six grassroots meetings and one international meeting to discuss generally the President's recently announced initiative to ensure the safety of imported and domestic fruits and vegetables and other foods, and specifically the microbial safety of produce. The meetings are intended to give an overview of, and obtain input on the general draft guide entitled ''Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruit and Vegetables.''

DATES AND TIME: For the domestic meetings see Table 1 in the ''**SUPPLEMENTARY INFORMATION**'' section of this document. For the international meeting see Table 2. Submit written comments by December 19, 1997. All the meetings will be held from 9 a.m. to 4 p.m.

ADDRESSES: For the domestic meetings see Table 1 in the ''**SUPPLEMENTARY INFORMATION**'' section of this document. For the international meeting see Table 2. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Copies of the ''Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruit and Vegetables'' may be obtained from Joan E. Duy, Center for Food Safety and Applied Nutrition (HFS–335), Food and Drug Administration, 200 C St. SW., rm. 3812, Washington, DC 20204, 202–260–8920, FAX 202–205–4422, e-mail jduy@bangate.fda.gov.

FOR FURTHER INFORMATION CONTACT: *For general information on this document*: Camille E. Brewer, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., rm. 3169, Washington, DC, 202–260–8920, FAX 202–205–4422, e-mail ceb@cfsan.fda.gov. Send registration information (including name, title, firm name, mailing address, telephone number and fax number if appropriate) to the contact person listed for the city in which you will attend.

SUPPLEMENTARY INFORMATION: On October 2, 1997, the President announced an initiative to ensure the safety of imported and domestic produce and other foods. This initiative is geared to optimize the microbial safety of domestic and imported fresh fruits and vegetables. As part of this initiative, the President directed the Secretary of the Department of Health and Human Services (DHHS), in partnership with the Secretary of the Department of Agriculture (USDA), and in cooperation with the agricultural community, to issue advice on good agricultural practices and good manufacturing practices for fresh fruits and vegetables. FDA will coordinate the effort for DHHS. As part of this effort, FDA plans to publish for public

comment a draft guide early in 1998, and a final guide later in 1998.

On November 17, 1997, at a public meeting in Washington, DC, FDA and USDA provided details on a broad, general draft approach on how to minimize microbial contamination through the control of water, manure, worker sanitation and health, field and facility sanitation, and transportation and handling. A draft guide entitled ''Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruit and Vegetables,'' will be available December 1, 1997, on FDA's World Wide Web Home Page (http//www.fda.gov).

The grassroots and the international meetings will include an overview of the President's initiative and a review of the general draft guide. The meetings are intended to obtain input into the draft guide. While all meetings are open to any interested parties, the grassroots meetings will focus specifically on domestic produce, and the international meeting will focus on imported produce.

Transcripts of the grassroots and international meetings may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximated 15 working days after each meeting at a cost of 10 cents per page. The transcripts of the grassroots and the international meetings will be available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

TABLE 1.—DOMESTIC MEETINGS

Meeting Address	Date	FDA Contact Person
GRAND RAPIDS: Amway Grand Hotel, Pearl and Monroe, Grand Rapids, MI..	December 1, 1997	Evelyn Denke, Food and Drug Administration, Detroit District Office (HFR–MW245), 1500 E. Jefferson Ave., Detroit, MI 48207–3179, 313–226–6158.
GENEVA: New York State Agricultural Experiment Station, 630 West North St., Geneva, NY..	December 3, 1997	Beverly Kent, Food and Drug Administration, Buffalo District Office, 599 Delaware Ave., Buffalo, NY 14202, 716–551–4461 ext. 3131.
WEST PALM BEACH: Clayton Hutchinson Agricultural Center, 559 North Military Trail, West Palm Beach, FL..	December 5, 1997	Lynn Isaacs, Food and Drug Administration, Florida District Office, 7200 Lake Ellenor Dr., suite 120, Orlando, FL 32809, 407–648–6922 ext. 202.
SAN ANTONIO: Helotes 4–H Center, San Antonio, TX, 12132 Leslie Rd., Helotes, TX..	December 8, 1997	Sylvia Yetts, Food and Drug Administration, Dallas District Office (HFR–SW100), 3310 Live Oak St., Dallas, TX 75204, 214–655–5315 ext. 344.
SALINAS: Salinas Community Center, 490 North Main St., Salinas, CA..	December 10, 1997	Mary Acton, Food and Drug Administration, San Francisco District Office (HFR–PA150), 1431 Harbor Bay Pkwy., Alameda, CA 94502, 510–337–6765.
PORTLAND: Monarch Hotel, 12566 SE. 93d Ave., Clackamas, OR..	December 12, 1997	Debra Tucker, Food and Drug Administration, Portland District Office, 9780 SW. Nimus Ave., Beaverton, OR 97008, 503–671–9711 ext. 10.

TABLE 2.—INTERNATIONAL MEETING

Meeting Address	Date	FDA Contact Person
WASHINGTON, DC: Department of Health and Human Services, Hubert Humphrey Bldg., 200 and Independence, Washington, DC..	Monday, December 8, 1997	Marilyn Veek, Food and Drug Administration, Office of International Affairs (HFG–1), 5600 Fishers Lane, Rockville, MD 20857, 301–827–0906

Dated: November 24, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–31366 Filed 11-25-97; 11:18 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 97F–0468]

Ciba Specialty Chemicals Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba Specialty Chemicals Corp., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of tris(2,4-di-*tert*-butylphenyl)phosphite by removing the restrictions on the temperature of use in low density polyethylene films of thickness greater than 0.051 millimeter (mm) (0.002 inch (in)), provided that the film does not contain a total of tris(2,4-di-*tert*-butylphenyl)phosphite in excess of 0.062 milligram (mg) per in^2 of the food-contact surface.

DATES: Written comments on petitioner's environmental assessment by December 29, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch