DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F–0388]

Cultor Food Science, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Cultor Food Science, Inc., has filed a petition proposing that the food additive regulations be amended to permit aqueous transition metal catalytic hydrogenation in the production of polydextrose and to adopt the specifications for polydextrose of the Food Chemicals Codex, 4th ed., 1996.

DATES: Written comments on the petitioner's environmental assessment by October 27, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rosalie M. Angeles, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3107.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 7A4556) has been filed by Cultor Food Science, Inc., 205 East 42d St., New York, NY 10017. The petition proposes to amend the food additive regulations in § 172.841 *Polydextrose* (21 CFR 172.841) to permit aqueous transition metal catalytic hydrogenation in the production of polydextrose and to adopt the specifications for polydextrose of the Food Chemicals Codex, 4th ed., 1996, pp. 297–300.

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 October 27, 1997 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 public display any amendments to, or comments on, the petitioner's 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: September 9, 1997.

Alan M. Rulis,

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

[FR Doc. 97–25368 Filed 9–24–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 97F–0405]

Shikoku Chemical Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Shikoku Chemical Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of aluminum borate as an antistatic agent and/or antifogging agent for olefin polymers intended for use as packaging materials in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 7B4559) has been filed by Shikoku Chemical Corp., c/o SRS International Corp., suite 1000, 1625 K St. NW., Washington DC 20006–1604. The petition proposes to amend the food additive regulations in § 178.3130 Antistatic and/or antifogging agents in food-packaging materials (21 CFR 178.3130) to provide for the safe use of aluminum borate as an antistatic and/or antifogging agent for olefin polymers complying with 21 CFR 177.1520(c) as packaging materials intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: September 11, 1997.

Alan M. Rulis,

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

[FR Doc. 97–25430 Filed 9–24–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0399]

Helen A. Ballack Co. et al.; Withdrawal of Approval of 61 New Drug Applications, 8 Abbreviated Antibiotic Applications, and 36 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 61 new drug applications (NDA's), 8 abbreviated antibiotic applications (AADA's), and 36 abbreviated new drug applications (ANDA's). The holders of the applications 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: September 25, 1997.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The holders of the applications 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.

Application No.	Drug	Applicant
NDA 4–526	Bal-Con Capsules	Helen A. Ballack Co., 1356 Book Bldg., Detroit, MI 48226.
NDA 6–203	Nupercaine Heavy Solution (dibucaine hydrochloride)	Novartis Pharmaceuticals Corp., 59 Rt. 10, East Hanover, NJ 07936–1080.
NDA 6–514	Benylin (diphenhydramine hydrochloride) Cough Syrup 12.5 milligrams (mg)/milliliter (mL)	Warner-Lambert Co., 170 Tabor Rd., Morris Plains, NJ 07950.
NDA 6–550	ORTHOXICOL Cough Syrup	The Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199.
NDA 6–658	Floropryl (isoflurophate ophthalmic solution) Ophthalmic Solution	Merck & Co., Inc., P.O. Box 4, BLA–20, West Point, PA 19486.
NDA 6–921	CHLOR-TRIMETON (chlorpheniramine maleate) Tablets and Syrup	Schering-Plough Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 7–635	NPH Insulin	Merck Sharp & Dohme, Division of Merck & Co., Inc.
NDA 7–757	Gantrisin (sulfoxazole diolamine ophthalmic solution) Ophthalmic Solution	Hoffman-LaRoche, Inc., 340 Kingsland St., Nutley, NJ 07110–1199.
NDA 9–018	Hydrocortone Acetate Ophthalmic Solution and Ophthalmic Ointment	Merck & Co., Inc.
NDA 10–656	Floropryl (isoflurophate ophthalmic ointment) Ophthalmic Ointment	Do.
NDA 11–185	Reserpine Tablets USP, 0.1 mg and 0.25 mg	Zenith Goldline Pharmaceuticals, Inc., 140 Legrand Ave., Northvale, NJ 07647.
NDA 11–300	Paraflex (chlorzoxazone tablet) Caplets, 250 mg	R. W. Johnson Pharmaceutical Research Institute, 920 Rt. 202 South, P.O. Box 300, Raritan, NJ 08860–0602.
NDA 11–521	Rauwolfia Serpentine Tablets USP, 50 mg and 100 mg	Zenith Goldline Pharmaceuticals, Inc.
NDA 11–919	Otrivin (xylometazoline hydrochloride)	Novartis Pharmaceuticals, Corp., 59 Rt. 10, East Hanover, NJ 07936–1080.
NDA 17–313	Iodohippurate Sodium I–131 Injection	CIS–US, Inc., 10 De Angelo Dr., Bedford, MA 01730.
NDA 17–672	Lithonate Syrup (Lithium Citrate Syrup, USP)	Solvay Pharmaceuticals, Inc., 901 Sawyer Rd., Marietta, GA 30062.
NDA 17–792	AN–MAA, Technetium TC 99m Albumin Aggregated Kit	CIS–US, Inc.
NDA 17–996	Semilente Insulin (prompt insulin zinc suspension, USP (Beef))	Novo Nordisk Pharmaceuticals, Inc., suite 200, 100 Overlook Center, Princeton, NJ 08540–7810.
NDA 17–997	Ultralente Insulin (extended insulin zinc suspension, USP (Beef))	Novo Nordisk.
NDA 18–125	Halog (halcinonide ointment) Ointment, 0.025%	Bristol-Myers Squibb Pharmaceutical Research Institute, P.O. Box 4000, Princeton, NJ 08543–4000.
NDA 18–055	3.3% Dextrose and 0.3% Sodium Chloride Injection in Flexible Containers	Abbott Laboratories, D–389 Bldg. AP30, 200 Abbott Park Rd., Abbott Park, IL 60064–3537.
NDA 18–384	Lentard (Purified pork and beef insulin zinc suspension)	Novo Nordisk.
NDA 18–462	Ringer's Irrigation in Flexible Containers	Abbott Laboratories.
NDA 18–525	Purified beef insulin zinc suspension	Novo Nordisk.
NDA 18–526	Isophane purified beef insulin suspension	Do.
NDA 18–528	Purified pork insulin injection	Do.
NDA 18–804	Aminosyn 3.5% and 3.5%M in Flexible Containers	Abbott Laboratories.
NDA 18–875	Aminosyn 3.5% and 3.5%M in CR3 Flexible Containers	Do.
NDA 18–923	38.5% Dextrose Injection in Flexible Containers	Do.
NDA 19–065	Novolin N NPH Human Insulin Isophane Suspension (semi-synthetic)	Novo Nordisk.
NDA 19–118	Aminosyn 3.5% and 25% Dextrose Injection	Abbott Laboratories.
NDA 19–119	Aminosyn 4.25% and 25% Dextrose Injection	Do.
NDA 19–120	Aminosyn 3.5% and 5% Dextrose Injection	Do.
NDA 19–218	0.9% Sodium Chloride Injection in Plastic Vials	Do.
NDA 19–339	Heparin Sodium in 5% Dextrose Injection in CR3 Flexible Container	Do.
NDA 19–400	Aminosyn-HBC 7% in CR3 Flexible Containers	Do.
NDA 19–449	Insulatard NPH Human (human insulin (semi-synthetic) isophane suspension)	Novo Nordisk.
NDA 19–482	5% Dextrose and 0.225% Sodium Chloride Injection in 250 mL ADD-Vantage Flexible Containers	Abbott Laboratories.
NDA 19–483	5% Dextrose and 0.9% Sodium Chloride Injection in 250 mL ADD-Vantage Flexible Containers	Do.
NDA 19–484	5% Dextrose and 0.45% Sodium Chloride Injection in 250 mL ADD-Vantage Flexible Containers	Do.
NDA 19–485	Lactated Ringer's Injection in 250 mL ADD-Vantage Flexible Containers	Do.
NDA 19–486	5% Dextrose and 0.3% Sodium Chloride Injection in 250 mL ADD-Vantage Flexible Containers	Do.
NDA 19–491	Aminosyn II 3.5% in CR3 Flexible Containers	Do.
NDA 19–493	Aminosyn II 3.5M in CR3 Flexible Containers	Do.

Application No.	Drug	Applicant
NDA 19–504	Aminosyn II 4.25% w/25% Dextrose in Dual-Chamber Flexible Container	Do.
NDA 19–505	Aminosyn II 3.5% w/25% Dextrose in CR3 Dual-Chamber Flexible Container	Do.
NDA 19–506	Aminosyn II 3.5% w/5% Dextrose in CR3 Dual-Chamber Flexible Container	Do.
NDA 19–712	Aminosyn II w/Electrolytes in Dextrose Injection in 2000 mL CR3 Flexible Container	Do.
NDA 19–713	Aminosyn II in Dextrose Injection in CR3 Flexible Containers	Do.
NDA 19–714	Aminosyn II w/Electrolytes in Dextrose Injection w/Calcium in 2000 mL CR3 Flexible Container	Do.
NDA 19–837	Bretylium Tosylate in 5% Dextrose Injection in Plastic Container, PL 146	Baxter Healthcare Corp., Rt. 120 and Wilson Rd., Round Lake, IL 60073–0490.
NDA 20–043	OMNIFLOX (temafloxacin hydrochloride) Filmtab Tablets	Abbott Laboratories.
NDA 50–188	VINACTANE (sterile viomycin sulfate)	Novartis Pharms, 556 Morris Ave., Summit, NJ 07901.
NDA 50–019	Penbritin Drops	Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101–8299.
NDA 50–028	DYNAPEN (Dicloxacillin sodium menohydrate) Capsules	Bristol-Myers, U.S. Pharmaceutical Group, Evansville, IN 47721–0001.
NDA 50–029	Hetacillin Potassium, Sterile	Bristol-Myers Squibb Co., P.O. Box 4755, Syracuse, NY 13221–4755.
NDA 50–134	SYNCILLIN (phenethicillin potassium) O.S.	Bristol-Myers, U.S. Pharmaceutical Group.
NDA 50–328	Methicillin Sodium	Bristol-Myers Squibb Co.
NDA 50–378	Neohydeltrasol (neomycin sulfate/prednisolone sodium sulfate ophthalmic ointment) Ophthalmic Ointment	Merck & Co., Inc.
NDA 50–562	Azlin (azlocillin sodium)	Miles, Pharmaceutical Division, 400 Morgan Lane, West Haven, CT 06516–4175.
NDA 50–618	AMIKIN (amikacin sulfate) in 0.9% NaCL (PVC flexible containers)	Apothecon, P.O. Box 4500, Princeton, NJ 08543–4500.
AADA 60–291	Tetracycline Oral Suspension USP, 125 mg/5 mL	Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207.
AADA 62–218	Ampicillin Trihydrate, bulk drug	ACS Dobfar SpA, U.S. Agent: Interchem Corp., 120 Rt. 17 North, P.O. Box 1579, Paramus, NJ 07653–1579.
AADA 62–319	Tetracycline Hydrochloride (bulk, nonsterile)	Tianjin Pharmaceuticals Corp., U.S. Agent: Darsheng Trade & Tech. Dev. Co., Ltd., P.O. Box 1220, 655 Amboy Ave., A-wing, 1st Fl., Woodbridge, NJ 07095.
AADA 62–387	Nystatin Cream USP, 100,000 Units/g	Alpharma, U.S. Pharmaceuticals Div., Johns Hopkins Bayview Center, 333 Cassell Dr., suite 3500, Baltimore, MD 21224.
AADA 62–571	Nystatin Oral Suspension USP, 100,000 Units/mL	Do.
AADA 62–731	Nystatin Ointment USP, 100,000 Units/g	Do.
AADA 62–809	Cephalexin Capsules USP, 250 mg and 500 mg	Purepac Pharmaceutical.
AADA 62–942	Cyclacilin, bulk drug	ACS Dobfar SpA.
ANDA 70–580	Allopurinol Tablets, USP, 300 mg	Purepac Pharmaceutical.
ANDA 71–085	Betamethasone Dipropionate Lotion USP, 0.05%	Alpharma.
ANDA 71–798	Triprolidine and Pseudo-ephedrine Hydrochlorides Extended-Release Capsules, 5 mg/120 mg	KV Pharmaceutical Co., 2503 South Hanley Rd., St. Louis, MO 63144–2555.
ANDA 71–924	Clorazepate Dipotassium Capsules, 3.75 mg	Purepac Pharmaceutical.
ANDA 71–925	Clorazepate Dipotassium Capsules, 7.5 mg	Do.
ANDA 71–926	Clorazepate Dipotassium Capsules, 15 mg	Do.
ANDA 80–087	Sulfisoxazole Tablets USP, 500 mg	Do.
ANDA 80–395	Hydrocortisone Tablets, 20 mg	Do.
ANDA 83–271	Niacin Tablets, 500 mg	Do.
ANDA 84–020	Triamcinolone Tablets USP, 4 mg	Do.
ANDA 84–247	Hydrocortisone Tablets, 10 mg	Do.
ANDA 84–804	Meprobamate Tablets USP, 200 mg and 400 mg	Do.
ANDA 84–939	Chlordiazepoxide Hydrochloride Capsules USP, 10 mg	Do.
ANDA 85–144	Chlordiazepoxide Hydrochloride Capsules USP, 25 mg	Do.
ANDA 85–155	Chlordiazepoxide Hydrochloride Capsules USP, 5 mg	Do.
ANDA 85–753	Liothyronine Sodium Tablets, 50 micrograms	Bolar Pharmaceutical Co., Inc., 130 Lincoln St., Copiague, NY 11726.
ANDA 85–904	Isoproterenol Hydrochloride Inhalation Aerosol USP, 0.25%	Alpharma.
ANDA 86–110	Sustachron (Nitroglycerin Extended-release) Oral Tablets, 6.5 mg	Forest Laboratories, Inc., 909 Third Ave., New York, NY 10022–4731.
ANDA 86–112	Sustachron (Nitroglycerin Extended-release) Oral Tablets, 2.6 mg	Do.
ANDA 86–649	Sustachron (Nitroglycerin) Tablets, 10 mg	Do.
ANDA 87–110	Nitroglycerin Extended-release Capsules	KV Pharmaceutical Co.
ANDA 87–683	Pentaerythritol Tetra-nitrate Extended-release Capsules, 80 mg	Inwood Laboratories, Inc., 909 Third Ave., New York, NY 10022–4731.
ANDA 87–995	THEO–DUR (Theophylline Sustained-release Capsules) Sprinkle, 200 mg	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.

Application No.	Drug	Applicant
ANDA 88–015	THEO–DUR (Theophylline Sustained-release Capsules) Sprinkle, 75 mg	Do.
ANDA 88–016	THEO–DUR (Theophylline Sustained-release Capsules) Sprinkle, 125 mg	Do.
ANDA 88–022	THEO–DUR (Theophylline Sustained-release Capsules) Sprinkle, 50 mg	Do.
ANDA 88–066	Hydrocone Bitartrate and Homatropine Methylbromide Syrup, 5 mg/1.5 mg per5 mL	Halsey Drug Co., 1827 Pacific St., Brooklyn, NY 11233.
ANDA 88–112	Tripodrine (Triprolidine and Pseudoephedrine Hydrochlorides Tablets USP) 2.5 mg/60 mg	Danbury Pharmacal, Inc., 131 West St., Danbury, CT 06810.
ANDA 88–140	Chlorthalidone Tablets USP, 50 mg	Purepac Pharmaceutical.
ANDA 88–178	Hydralazine Hydrochloride Tablets, 50 mg	Do.
ANDA 88–360	Fluocinolone Acetonide Cream USP, 0.025%	Alpharma.
ANDA 88–361	Fluocinolone Acetonide Cream USP, 0.01%	Do.
ANDA 88–950	Tolbutamide Tablets, 500 mg	Purepac Pharmaceutical.
ANDA 88–997	Dexamethasone Elixir USP, 0.5 mg/5 mL	Alpharma.
ANDA 89–754	Hydrocortisone Cream USP, 2.5%	Do.
ANDA 89–840	Procainamide Hydrochloride Extended-release Tablets, 500 mg	Inwood Laboratories.

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 September 25, 1997.

Dated: September 11, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–25369 Filed 9–24–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Delegation of Authority

Notice is hereby given that I have delegated to the Director, Centers for Disease Control and Prevention, with authority to redelegate, the following authorities vested in the Secretary of Health and Human Services under Title XXVI of the Public Health Service Act, ''Health Care Services Program,'' and the Ryan White Care Act Amendments of 1996 (P.L. 104–146), as amended hereafter, insofar as these authorities pertain to the functions assigned to the Centers for Disease Control and Prevention:

Section 2625—CDC Guidelines for Pregnant Women

Section 2626—Perinatal Transmission of HIV Disease; Contingent Requirement Regarding State Grants Under This Part

Section 2628—Report by the Institute of Medicine

Sections 2641–2650—Formula Grants for States

Sections 2661–2667—General Provisions

Section 2675—Coordinaiton

Section 2680—Grants to States and political subdivisions of States to implement guidelines and model curriculum for health workers and public safety workers, including emergency response employees.

Sections 2681–2690—Notificaiton of Possible Exposure to Infectious Diseases

The Centers for Disease Control and Prevention and the Health Resources and Services Administration shall cooperate in the implementation of Section 2626(e).

This delegation shall be excised under the Department's existing delegation of authority and policy on regulations.

This delegation became effective upon date of signature. In addition, I have affirmed and ratified any actions taken by the Director, Centers for Disease Control and Prevention or his subordinates which involved the exercise of the authorities delegated herein prior to the effective date of the delegation.

Dated: September 15, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 97–25467 Filed 9–24–97; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–97]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Requirement to Disclose HMO Financial Information to Members and Supporting Regulations in 42 CFR 417.124; *Form No.:* HCFA–R–0097 (OMB 0938–0472); *Use:* Federally