growth between the smoking process and distribution at retail, and (3) recontamination with *L. monocytogenes* during the manufacturing and/or processing of smoked finfish.

Listeria monocytogenes contamination is a problem in cold-smoked finfish because the heat applied during processing is not sufficient to inactivate the organism, and the fish are consumed without further cooking. Cold-smoked finfish may become contaminated during processing due to inadequate sanitation, particularly because of insufficient cleaning and sterilizing of the slicer. For hot-smoked finfish, although *L. monocytogenes* is killed by adequate hot-smoking, recontamination after hot-smoking can result in high numbers of the organism in the finished products. Additionally, the ability of the organism to grow under both refrigerated aerobic and anaerobic conditions makes it a concern in products packed in permeable wrappers and under modified atmosphere or vacuum. This sealing of the product extends shelf-life and, therefore, provides additional time for the organism to grow.

Preventive Controls for L. monocytogenes in Retail and Foodservice Establishments: FDA is evaluating the Food Code to determine whether it should consider recommending revisions to the provisions addressing preventive controls for *L. monocytogenes* in retail and foodservice establishments. Specifically, FDA will take the following steps: (1) Review the Food Code to determine whether it should consider recommending revisions to the provisions that address preventive controls, such as approved source, date marking, and cold holding times and temperatures; and (2) in conjunction with the Conference for Food Protection, issue guidance to the retail and food service industries and State and local regulatory professionals on the use of Hazard Analysis Critical Control Point (HACCP) principles to identify and control risk factors contributing to foodborne illness. FDA intends for such guidance to discuss intervention strategies that industry can use to control *L. monocytogenes* and other pathogens.

II. Request for Comments and for Scientific Data and Information

Smoked Finfish Risk Assessment: FDA requests comments on the risk assessment approach outlined previously in this document and the submission of data and any information relevant to this risk assessment. The agency specifically requests information for the following: (1) *L. monocytogenes* levels in raw fish, smoked fish, and finished product; (2) effect of mitigation measures (e.g., ozonation, acidified sodium chlorite) to reduce *L. monocytogenes* levels in raw and finished product; (3) potential for transfer of *L. monocytogenes* to food from contaminated food contact and noncontact surfaces during manufacturing and/or processing (e.g., equipment, workers, floor drains, etc.); (4) potential for transfer of *L. monocytogenes* from the slicer to cold-smoked fish; (5) impact of adding inhibitors (e.g., bacteriocins and bacteriocins-producing bacterial strains or sodium lactate) to smoked finfish to reduce or prevent *L. monocytogenes* growth; (6) impact of frozen versus refrigerated storage conditions on levels of *L. monocytogenes*; (7) impact of time and temperature on levels of *L. monocytogenes* for commercial and home storage conditions of finished product; and (8) effect of training regarding sanitation and hygienic practices on reducing the levels of *L. monocytogenes* in smoked finfish.

Preventive Controls for L. monocytogenes in Retail and Foodservice Establishments: Under the FDA/CDC *Listeria* Action Plan, FDA is continuing its commitment to review the Food Code to determine whether it should consider recommending revisions to the provisions that address preventive controls for *Listeria* in retail and foodservice establishments. The agency specifically requests the following data and information: (1) *L. monocytogenes* levels in products stored in retail and foodservice establishments; (2) levels of environmental contamination and harborage of *L. monocytogenes* on food contact and nonfood contact surfaces in retail and foodservice establishments (e.g., equipment, workers, floor drains, etc.); (3) effects of short- and long-term refrigerated storage on levels of *L. monocytogenes* in retail and foodservice establishments; (4) impact of time and temperature on levels of *L. monocytogenes* in products stored in retail and foodservice establishments; (5) efficacy of cleaning procedures and sanitizing agents on environmental surfaces and utensils; (6) frequency of use and impact of adding inhibitors to food products in retail and foodservice establishments to reduce or prevent *L. monocytogenes* growth; and (7) effect of training regarding hygienic practices and sanitation on levels of *L. monocytogenes* in products in retail and foodservice establishments.

Interested persons should submit comments, scientific data, and information to the Division of Dockets Management (see **ADDRESSES**). Three copies of all comments, scientific data, and information are to be submitted. Individuals submitting written information or anyone submitting electronic comments may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by supporting information. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Information submitted after the closing date will not be considered except by petition under 21 CFR 10.30.

III. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Department of Health and Human Services, *Healthy People 2010*, v. 1. Washington, DC, 2000, *http://www.healthypeople.gov*.

2. U.S. Department of Health and Human Services and U.S. Department of Agriculture/Food Safety and Inspection Service, ''Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods,'' September 2003, *http://www.foodsafety.gov/~dms/lmr2–toc.html*.

3. U.S. Department of Health and Human Services, Food and Drug Administration/Centers for Disease Control and Prevention, ''Reducing the Risk of *Listeria monocytogenes* FDA/CDC 2003 Update of the *Listeria* Action Plan,'' November 2003, *http://www.cfsan.fda.gov/~dms/lmr2plan.html*.

4. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, *Food Code*, 2001, *http://www.cfsan.fda.gov/~dms/fc01–toc.html*.

Dated: February 25, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–4217 Filed 3–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0058]

Hospira, Inc. et al.; Withdrawal of Approval of 76 New Drug Applications and 60 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 76 new drug applications (NDAs) and 60 abbreviated new drug applications (ANDAs) from multiple applicants. 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: April 4, 2005.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, 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 requests, waived their opportunity for a hearing.

Application No.	Drug	Applicant
NDA 6–095	Tubocurarine Chloride Injection	Hospira, Inc., 275 North Field Dr., Bldg. 2–J45–2, Lake Forest, IL 60045–5046
NDA 6–412	Decapryn (doxylamine succinate) Tablets and Syrup	Aventis Pharmaceuticals, Inc., 200 Crossing Blvd., Bridgewater, NJ 08807–0890
NDA 6–460	Protamine Sulfate Injection USP	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285
NDA 8–032	Telepaque (iopanoic acid) Tablets	Amersham Health, 101 Carnegie Center, Princeton, NJ 08540
NDA 10–288	Betadine (10% povidone iodine) Solution and Isodine (10% povidone iodine) Solution	The Purdue Frederick Co., One Stamford Forum, Stamford, CT 06901–3431
NDA 11–097	Dimetane (brompheniramine maleate) Elixir	Wyeth Consumer Healthcare, Five Giralda Farms, Madison, NJ 07940
NDA 11–270	Furoxone (furazolidone) Tablets	Shire Laboratories, Inc., c/o Shire Pharmaceutical Development, Inc., 1801 Research Blvd., suite 600, Rockville, MD 20850
NDA 11–323	Furoxone (furazolidone) Oral Suspension	Do.
NDA 11–325	Vesprin (triflupromazine hydrochloride (HCl)) Injection, 10 milligrams (mg)/milliliter (mL) and 20 mg/mL	Apothecon, c/o Bristol-Myers Squibb Co., P.O. Box 4500, Princeton, NJ 08543–4500
NDA 11–367	Enzactin (triacetin) Spray	Wyeth Consumer Healthcare
NDA 12–265	Naqua (trichlormethiazide) Tablets and Naquival (trichlormethiazide and reserpine) Tablets	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033
NDA 12–320	Rauzide (rauwolfia serpentine with bendroflumethiazide) Tablets and Rautrax-N Tablets	Apothecon, c/o Bristol-Myers Squibb Co.
NDA 12–728	Ortho-Novum 1/50–21 (norethindrone and mestranol) Tablets	Ortho-McNeil Pharmaceuticals, Inc., c/o Johnson & Johnson Research and Development, L.L.C., 920 Route 202 South, Box 300, Raritan, NJ 08869–0602
NDA 16–993	Adsorbotear Ophthalmic Solution	Alcon Laboratories, Inc., 6201 South Freeway, Fort Worth, TX 76134
NDA 17–471	Sodium Pertechnetate Tc–99m (technetium Tc–99m sodium pertechnetate) Solution	Amersham Health
NDA 17–488	Modicon 21 (norethindrone and ethinyl estradiol) Tablets	Ortho-McNeil Pharmaceuticals, Inc., c/o Johnson & Johnson Research and Development, L.L.C.
NDA 17–489	Ortho-Novum 1/35–21 (norethindrone and ethinyl estradiol) Tablets and Neocon Tablets (norethindrone and ethinyl estradiol)	Do.
NDA 17–561	Celstone (betamethasone sodium phosphate USP) Injection	Schering Corp.
NDA 17–601	Optimine (azatadine maleate USP) Tablets	Do.

Application No.	Drug	Applicant
NDA 17–603	Novafed ER (pseudoephedrine HCl) Tablets, 120 mg	Aventis Pharmaceuticals, Inc.
NDA 17–657	Cephulac (lactulose fumarate) Syrup	Do.
NDA 17–661	Tavist (clemastine fumarate) Tablets and Tavist–1 (clemastine fumarate) Tablets	Novartis Consumer Health, Inc., 200 Kimball Dr., Parsippany, NJ 07054–0622
NDA 17–687	Xenon Xe–133 Gas	Amersham Health
NDA 17–700	Gallium Citrate Ga–67 Injection	Do.
NDA 17–773	Technetium Tc–99m MAA Kit	Amersham Health
NDA 17–884	Chronulac (lactulose) Syrup	Aventis Pharmaceuticals, Inc.
NDA 18–030	Dextrose and Sodium Chloride (NaCl) Injection USP	B. Braun Medical, Inc., 2525 McGaw Ave., P.O. Box 19791, Irvine, CA 92623–9791
NDA 18–062	Proventil (albuterol sulfate) Syrup	Schering Corp.
NDA 18–229	Dextrose and NaCl Injection USP	B. Braun Medical, Inc.
NDA 18–269	Isolyte E (multi-electrolyte injection) with 5% Dextrose	Do.
NDA 18–270	Isolyte M (multi-electrolyte injection) with 5% Dextrose	Do.
NDA 18–271	Isolyte R (multi-electrolyte injection) with 5% Dextrose	Do.
NDA 18–273	Isolyte H (multi-electrolyte injection) with 5% Dextrose	Do.
NDA 18–335	Amerscan (technetium Tc–99m medronate) MDP Kit	Amersham Health
NDA 18–358	Dextrose Injection USP, 2.5%	B. Braun Medical, Inc.
NDA 18–386	Dextrose and NaCl Injection USP	Do.
NDA 18–506	Trinalin Repetabs (azatadine maleate and pseudoephedrine sulfate tablets)	Schering Corp.
ANDA 18–621	Nitro-Bid IV (nitroglycerin) Injection, 5 mg/mL	Aventis Pharmaceuticals, Inc.
NDA 18–654	Versed (midazolam HCl) Injection	Hoffman-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110–1199
NDA 18–675	Tavist (clemastine fumarate) Syrup	Novartis Consumer Health, Inc.
ANDA 18–889	Metronizadole in NaCl Injection	Abbott Laboratories, 200 Abbott Park Rd., D–389 J45–2, Abbott Park, IL 60064–6133
NDA 18–899	Isolyte E (multi-electrolyte injection)	B. Braun Medical, Inc.
NDA 18–924	Aminophylline in 0.45% NaCl Injection	Hospira, Inc.
NDA 18–967	Lidocaine HCl and 5% Dextrose Injection	B. Braun Medical, Inc.
NDA 19–004	Ortho-Novum (nonrethindrone and ethinyl estradiol) 7/14-21 and -28 Tablets	Ortho-McNeil Pharmaceuticals, Inc., c/o Johnson & Johnson Research and Development, L.L.C.
NDA 19–006	Isolyte S, pH 7.4 (multi-electrolyte injection)	B. Braun Medical, Inc.
NDA 19–025	Isolyte P (multi-electrolyte injection) with 5% Dextrose Do.	
NDA 19–033	Bretylium Tosylate Injection	Hospira, Inc.
NDA 19–042	Heparin Sodium in NaCl Injection	B. Braun Medical, Inc.
NDA 19–077	Sterile Water for Injection USP	Do.

Application No.	Drug	Applicant
NDA 19–134	Heparin Sodium in 5% Dextrose Injection	Do.
NDA 19–135	Heparin Sodium in 0.9% NaCl Injection	Do.
NDA 19–243	Proventil (albuterol sulfate) Inhalation Solution	Schering Corp.
NDA 19–471	Cardizem SR Capsules (diltiazem HCl), 60 mg, 90 mg, 120 mg, and 180 mg	Biovail Laboratories, Inc., c/o Biovail Technologies Ltd., 700 Route 202/206 North, Bridgewater, NJ 08807–0980
NDA 19–478	Adalat (nifedipine) Capsules	Bayer Pharmaceuticals Corp., 400 Morgan Lane, West Haven, CT 06516–4175
NDA 19–604	Volmax (albuterol sulfate) Extended- Release Tablets	Muro Pharmaceuticals, Inc., 890 East St., Tewksbury, MA 01876–1496
NDA 19–616	Penetrex (enoxacin) Tablets	Aventis Pharmaceuticals, Inc.
NDA 19–698	Toradol (ketorolac tromethamine) Injection	Roche Palo Alto, LLC, c/o Hoffman-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110
NDA 19–817	Persantine (dipyridamole) Injection	Boehringer Ingleheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877–0368
NDA 19–978	Bupivacaine HCl Injection USP	Hospira, Inc.
NDA 20–542	Dopamine HCl in 5% Dextrose Injection	Do.
NDA 20–677	Zagam (sparfloxacin) Tablets, 200 mg	Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504–4310
NDA 20–755	Caverject (alprostadil) Injection	Pfizer, Inc., 7000 Portage Rd., Kalamazoo, MI 49001
NDA 20–942	Versed (midazolam HCl) Syrup, 2 mg/mL	Hoffman-La Roche, Inc.
NDA 20–997	Chirocaine (levobupivacaine HCl) Injection	Purdue Pharma L.P., One Stamford Forum, Stamford, CT 06901–3431
NDA 50–010	Ilosone (erythromycin estolate oral suspension) Liquid	Eli Lilly & Co.
NDA 50–011	Pathocil (dicloxacillin sodium) Capsules	Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101–8299
NDA 50–199	Unipen (nafcillin sodium) Powder for Oral Solution	Do.
NDA 50–271	Achromycin (tetracycline HCl) Powder for Reconstitution	Lederle, c/o Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101–8299
NDA 50–320	Unipen (nafcillin sodium) Injection	Wyeth Pharmaceuticals
NDA 50–365	Ilosone (erythromycin estolate USP) Pulvules	Eli Lilly & Co.
NDA 50–369	Ilotycin (erythromycin) Tablets	Do.
NDA 50–426	Ilosone (erythromycin estolate USP) Tablets	Do.
NDA 50–427	Minocin (minocycline HCl) Diagnostic Susceptibility Powder	Lederle, c/o Wyeth Pharmaceuticals
NDA 50–437	Garamycin (gentamicin sulfate) Injection, 10 mg/mL	Schering Corp.
NDA 50–462	Unipen (nafcillin sodium) Tablets	Wyeth Pharmaceuticals
NDA 50–505	Garamycin (gentamicin sulfate) Injection, 2 mg/mL	Schering Corp.
NDA 50–549	Mezlin (mezlocillin sodium monohydrate) Sterile Powder for Injection	Bayer Pharmaceuticals Corp.

Application No.	Drug	Applicant
ANDA 60–134	Ledercillin VK (penicillin V potassium) Tablets, 250 mg and 500 mg	Lederle Laboratories, Pearl River, NY 10965
ANDA 60–136	Ledercillin VK (penicillin V potassium) for Oral Suspension, 125 mg/5 mL and 250 mg/5 mL	Do.
ANDA 60–413	Penicillin G Potassium Tablets	Wyeth Laboratories
ANDA 60–431	Ilosone (erythromycin estolate USP) Chewable Tablets	Lilly Research Laboratories, Lilly Corporate Center, Indianapolis, IN 46285
ANDA 60–559	Ilosone (erythromycin estolate) Oral Suspension Liquid	Do.
ANDA 60–625	Omnipen (ampicillin for oral suspension USP) for Oral Suspension	Wyeth Laboratories
ANDA 60–626	Omnipen-N (ampicillin sodium) Injection, 125 mg, 250 mg, 500 mg, 1 gram (g), and 2 g/vial	Do.
ANDA 61–655	Kantrex (kanamycin sulfate) Injection	Apothecon, c/o Bristol-Myers Squibb Co.
ANDA 61–675	Wyamycin S (erythromycin stearate tablets USP), 250 mg and 500 mg	Wyeth Laboratories
ANDA 61–685	Tetracycline HCl Capsules USP, 250 mg and 500 mg	Do.
ANDA 61–769	Cephapirin for Injection USP	Apothecon, c/o Bristol-Myers Squibb Co.
ANDA 61–893	Ilosone (erythromycin estolate USP) for Oral Suspension	Dista, c/o Lilly Research Laboratories, Lilly Corporate Center, Indianapolis, IN 46285
ANDA 61–894	Ilosone (erythromycin estolate) Oral Suspension	Do.
ANDA 61–895	Ilosone (erythromycin estolate USP) Chewable Tablets	Do.
ANDA 61–896	Ilosone (erythromycin estolate USP) Tablets	Do.
ANDA 61–897	Ilosone (erythromycin estolate USP) Pulvules	Do.
ANDA 61–910	Ilotycin (erythromycin) Enteric Coated Tablets	Do.
ANDA 62–123	Wyamycin E (erythromycin ethylsuccinate) Oral Suspension, 200 mg/5 mL and 400 mg/5 mL	Wyeth Laboratories
ANDA 62–131	Wymox (amoxicillin) for Oral Suspension	Do.
ANDA 62–501	Gentacidin Ophthalmic Ointment (gentamicin sulfate ophthalmic ointment USP) 0.3%	Novartis Ophthalmics, Inc., 11695 John Creek Pkwy., Duluth, GA 30097–1523
ANDA 62–544	Dexacidin (neomycin sulfate, polymyxin B sulfate, and dexamethasone) Ophthalmic Suspension	Novartis Pharmaceuticals Corp., One Health Plaza, Building 105 Eisenhower, East Hanover, NJ 07936
ANDA 62–566	Dexacidin (neomycin sulfate, polymyxin B sulfate, and dexamethasone) Ophthalmic Ointment	Novartis Ophthalmics, Inc.
ANDA 62–717	Unipen (nafcillin sodium) Injection, 500–mg, 1–g, and 2–g vials	Wyeth Laboratories
ANDA 62–718	Omnipen-N (ampicillin sodium) Injection, 125–mg, 250–mg, 500–mg, 1–g, and 2–g vials	Do.
ANDA 62–726	Kenamycin Sulfate Capsules USP, 500 mg	Apothecon, c/o Bristol-Myers Squibb Co.
ANDA 62–986	Cephalexin For Oral Suspension USP, 125 mg/5 mL	Do.
ANDA 63–107	Emgel (erythromycin) Topical Gel, 2%	GlaIxoSmithKline Consumer Healthcare, L.P., 1500 Littleton Rd., Parsippany, NJ 07054–3884

Application No.	Drug	Applicant
ANDA 71–159	Nitro-Bid (nitroglycerin) Injection, 10 mg/mL	Aventis Pharmaceuticals, Inc.
ANDA 74–194	Loperamide HCl Tablets, 2 mg	L. Perrigo Co., 515 Eastern Ave., Allegan, MI 49010
ANDA 74–539	Tamoxifen Citrate Tablets USP, 10 mg	Pharmachemie B.V., c/o Teva Pharmaceuticals, 1090 Horsham Rd., P.O. Box 1090, North Wales, PA 19454–1090
ANDA 75–114	Acyclovir Injection, 50 mg/mL	Abbott Laboratories
ANDA 75–583	Enalapril Maleate Tablets USP, 2.5 mg, 5 mg, 10 mg, and 20 mg	Apothecon Inc., c/o Bristol-Myers Squibb Co.
ANDA 75–729	Famotidine Injection, 0.4 mg/mL	Abbott Laboratories
ANDA 76–214	Sotalol HCl Tablets, 80 mg, 120 mg, and 160 mg	TorPharm, c/o Apotex Corp., 616 Heathrow Dr., Lincolnshire, IL 60069
ANDA 83–823	Nicolar (niacin) Tablets, 500 mg	Aventis Pharmaceuticals, Inc.
ANDA 83–892	Selenium Sulfide Lotion USP	Allergan, 2525 Dupont Dr., P.O. Box 19534, Irvine, CA 92623
ANDA 84–476	Domeboro (acetic acid, glacial and aluminum acetate) SolutionBayer Pharmaceuticals Corp.	
ANDA 85–113	Chlordiazepoxide HCl Capsules USP, 10 mg	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544
ANDA 85–187	Slo-Phyllin (theophylline) Syrup, 80 mg/15 mL	Aventis Pharmaceuticals, Inc.
ANDA 85–202	Slo-Phyllin (theophylline) Tablets, 100 mg	Do.
ANDA 85–204	Slo-Phyllin (theophylline) Tablets, 200 mg	Do.
ANDA 86–126	Nitrong SR (nitroglycerin) Tablets, 6.5 mg	Do.
ANDA 86–137	Nitrong (nitroglycerin) Ointment, 2%	Do.
ANDA 86–138	Nitrong (nitroglycerin) Tablets, 2.6 mg	Do.
ANDA 86–681	Acetaminophen and Codeine Phospate Tablets USP, 300 mg/30 mg	Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207
ANDA 87–715	Nitrong SR (nitroglycerin) Tablets, 9 mg	Do.
ANDA 87–892	Slo-Bid (theophylline) Capsules, 100 mg	Aventis Pharmaceuticals, Inc.
ANDA 87–893	Slo-Bid (theophylline) Capsules, 200 mg	Do.
ANDA 87–894	Slo-Bid (theophylline) Capsules, 300 mg	Do.
ANDA 88–082	Hydrocortisone USP, Micronized Powder (Non-sterile)	Paddock Laboratories, Inc., 3940 Quebec Ave. South, Minneapolis, MN 55427
ANDA 88–269	Slo-Bid (theophylline) Capsules, 50 mg	Aventis Pharmaceuticals, Inc.
ANDA 88–782	NTS 5 (nitroglycerin) Transdermal Systems	Hercon Laboratories Corp., 101 Sinking Springs Lake, P.O. Box 467, Emigsville, PA 17318
ANDA 88–783	NTS 15 (nitroglycerin) Transdermal Systems	Do.
ANDA 88–791	Vasocidin (sulfacetamide sodium and prednisolone acetate) Ophthalmic Ointment	Novartis Ophthalmics, Inc.
ANDA 89–047	Sulf–15 (sulfacetamide sodium ophthalmic solution USP), 15%	Do.
ANDA 89–516	NTS 10 (nitroglycerin) Transdermal Systems	Hercon Laboratories Corp.
ANDA 89–539	Slo-Bid (theophylline) Capsules, 75 mg	Aventis Pharmaceuticals, Inc.
ANDA 89–540	Slo-Bid (theophylline) Capsules, 125 mg	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, by the Commissioner, approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective April 4, 2005.

Dated: January 31, 2005.

Steven Galson,

Acting Director, Center for Drug Evaluation and Research.

[FR Doc. 05–4158 Filed 3–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0554]

Revised Compliance Policy Guide Regarding Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft revisions to Compliance Policy Guide (CPG) Sec. 110.310 entitled ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' The CPG provides written guidance to FDA and Customs and Border Protection (CBP) staff on enforcement of section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulations, which require prior notice for food imported or offered for import into the United States. The CPG has been revised to provide additional guidance to FDA and CBP staff regarding specific situations covering routine shipments of food that are transported through the United States, arriving from and exiting to the same country, and regarding the Harmonized Tariff Schedule (HTS) code that is part of the planned shipment information.

DATES: The draft revisions to the CPG are found in section C, items 7 and 8. Submit written or electronic comments concerning the draft revisions to the CPG by April 4, 2005. You may submit written or electronic comments on the other sections of the CPG at any time.

ADDRESSES: Submit written requests for single copies of the revised guidance to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent.

Submit written comments on the guidance to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Domenic Veneziano, Office of Regulatory Affairs (HFC–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 703–621–7809.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft revision to CPG Sec. 110.310 entitled ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' This revised guidance is issued with CBP concurrence and explains to FDA and CBP staff the new FDA and CBP policies on enforcement of section 307 of the Bioterrorism Act and its implementing regulations, which require prior notice to FDA of all food imported or offered for import into the United States (21 CFR part 1.276 through 1.285).

FDA is considering taking these steps while the prior notice final rule is under development to provide additional flexibility in filing prior notice when, due to the geography, the only practical transportation route available for the shipment is through the United States and when there is a prior notice violation because the prior notice does not include the 6-digit HTS code for the article of food.

FDA is issuing the revisions to the CPG as level 1 draft guidance consistent with FDA's good guidance practices regulation § 10.115 (21 CFR 10.115). The draft revisions to the CPG represent the agency's current thinking on its enforcement policy concerning prior notice. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. The draft revisions to the CPG are found in section C, items 7 and 8.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the revised CPG. Submit a single copy of electronic copies or two copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The revised CPG and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of the revised CPG is available on the Internet at *http://www.fda.gov/ora* under ''Compliance References.''

Dated: February 24, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–4218 Filed 3–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Organ Transplantation; Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill up to 13 vacancies on the Advisory Committee on Organ Transplantation (ACOT). The ACOT was established by the Amended Final Rule of the Organ Procurement and Transplantation Network (OPTN) (42 CFR Part 121) and, in accordance with Pub. L. 92–463, was chartered on September 1, 2000.

DATES: The agency must receive nominations on or before April 4, 2005.

ADDRESSES: All nominations should be submitted to the Executive Director, Advisory Committee on Organ Transplantation, Healthcare Systems Bureau, HRSA, Parklawn Building, Room 12C–06, 5600 Fishers Lane, Rockville, Maryland 20857. Federal Express, Airborne, UPS, etc., mail delivery should be addressed to Executive Director, Advisory Committee on Organ Transplantation, Healthcare Systems Bureau, HRSA, at the above address.