Additional Information

Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW, Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: March 22, 2000.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 00–7520 Filed 3–27–00; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 79F–0401]

Thomas J. Lipton, Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 0A3481) proposing that the food additive regulations be amended to provide for the safe use of methylene chloride as a solvent for decaffeinating tea.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3110.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of November 23, 1979 (44 FR 67231), FDA announced that a food additive petition (FAP 0A3481) had been filed by Thomas J. Lipton, Inc., 800 Sylvan Ave., Englewood Cliffs, NJ 07632. The petition proposed that the food additive regulations be amended to provide for the safe use of methylene chloride as a solvent for decaffeinating tea. Thomas J. Lipton, Inc., an operating division of Unilever, the successor to Thomas J. Lipton, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: March 15, 2000.

Laura M. Tarantino,

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

[FR Doc. 00–7538 Filed 3–27–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99P–4209]

Determination That Hydrocodone Bitartrate and Acetaminophen Tablets USP, 5 Milligrams/325 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that hydrocodone bitartrate and acetaminophen tablets USP, 5 milligrams (mg)/325 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for this drug product.

FOR FURTHER INFORMATION CONTACT: David T. Read, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments) authorizes the approval, under an abbreviated procedure, of duplicate versions of previously approved drug products. Sponsors of ANDA's do not have to repeat the extensive clinical testing necessary to gain approval of a new drug application (NDA). An ANDA sponsor must, with certain exceptions, show that the drug for which approval is sought contains the same active ingredient(s) in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments included what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is commonly referred to as the ''Orange Book.'' Drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)). Also, before an ANDA that refers to a listed drug may be approved, the agency must determine whether the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

Mallinckrodt, Inc., submitted a citizen petition dated September 27, 1999 (Docket No. 99P–4209/CP1), under 21 CFR 10.30(b) and 314.122(a), requesting that the agency determine whether hydrocodone bitartrate and acetaminophen tablets USP, 5 mg/325 mg, were withdrawn from sale for reasons of safety or effectiveness and, if not, to keep the drug in the Orange Book. Hydrocodone bitartrate and acetaminophen tablets USP, 5 mg/325 mg, are the subject of ANDA 40–099 held by UCB Pharma, Inc. ANDA 40–099 was approved on June 8, 1987, but the product was never marketed. FDA has determined, for purposes of §§ 314.161 and 314.162(c), that never marketing an approved drug product is equivalent to withdrawing the drug from sale.

FDA has reviewed its records and, under §§ 314.161 and 314.162(c), has determined that hydrocodone bitartrate and acetaminophen tablets USP, 5 mg/325 mg, were not withdrawn from sale for reasons of safety or effectiveness. FDA will, therefore, continue to list this product in the Orange Book's ''Discontinued Drug Product List,'' which lists, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to hydrocodone bitartrate and acetaminophen tablets USP, 5 mg/325 mg, may be approved by the agency.

Dated: March 20, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–7542 Filed 3–27–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1198]

John J. Ferrante et al.; Proposal to Withdraw Approval of 158 Abbreviated New Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on the agency's proposal to withdraw approval of 158 abbreviated new drug applications (ANDA's). The basis for the proposal is that the sponsors have repeatedly failed to file required annual reports for these applications.

DATES: Submit written requests for a hearing by April 27, 2000; submit data and information in support of the hearing request by May 30, 2000.

ADDRESSES: Requests for a hearing, supporting data, and other comments are to be identified with Docket No. 00N–1198 and submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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 approved applications to market new drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81). The holders of the applications listed in the following table have failed to submit the required annual reports and have not responded to the agency's request by certified mail for submission of the reports.

ANDA No.	Drug	Applicant
60–058	Chloramphenicol Capsules, 250 milligrams (mg).	John J. Ferrante, c/o Operations Management Consulting, 11 Fairway Lane, Trumbull, CT 06611.
60–062	Penicillin G Potassium.	The Upjohn Co., 700 Portage Rd., Kalamazoo, MI 49001.
60–094	Sterile Penicillin G Procaine Suspension USP.	Do.
60–110	Sterile Dihydrostreptomycin Sulfate USP.	Pfizer Central Research, Pfizer, Inc., Eastern Point Rd., Groton, CT 06340.
60–170	Penicillin G Potassium Tablets, 200,000, 250,000, and 400,000 units.	John J. Ferrante.
60–173	Tetracycline Hydrochloride (HCl) Capsules, 250 mg.	Do.
60–174	Tetracycline Oral Suspension, 125 mg/5 milliliters (mL).	Do.
60–177	Bacitracin-Neomycin Sulfate Polymyxin B Sulfate Ointment.	Do.
60–178	Bacitracin-Neomycin Sulfate Ointment.	Do.
60–179	Oxytetracycline HCl Capsules, 250 mg.	Do.
60–188	Neomycin Sulfate and Hydrocortisone Actetate Ophthalmic Suspension USP.	Akorn, Inc., c/o Walnut Pharmaceuticals, Inc., 1340 North Jefferson St., Anaheim, CA 92807.
60–360	Neomycin and Polymyxin B Sulfate and Bacitracin Ointment with Benzocaine.	Ambix Laboratories, 210 Orchard St., East Rutherford, NJ 07073.
60–435	Tetracycline HCl Tablets USP, 250 mg.	Farmitalia Carlo Erba S.p.A., c/o Montedison, USA, Inc., 1114 Avenue of the Americas, New York, NY 10036.
60–453	Neomycin and Polymyxin B Sulfate and Bacitracin Ointment with Diperodon HCl.	Ambix Laboratories.
60–464	Neomycin Sulfate and Prednisolone.	The Upjohn Co.
60–647	Neo-Polycin Opthalmic Ointment.	Merrell Dow Pharmaceuticals, Inc., P.O. Box 68511, Indianapolis, IN 46268.
60–666	Ampicillin Tihydrate for Oral Suspension.	Beecham Laboratories, 501 Fifth St., Bristol, TN 37620.
60–690	Oxytetracycline HCl.	Pierrel America, Inc., 576 Fifth Ave., New York, NY 10036.
60–720	Tetracycline HCl Capsules, 250 mg.	Towne Paulsen & Co., Inc., 140 East Duarte Rd., Monrovia, CA 91016.
60–757	Polymyxin B Sulfate, 500,000 units.	Burroughs Wellcome Co., 3030 Cornwallis Rd., Research Triangle Park, NC 27709.
60–774	Griseofulvin Tablets, 500 mg.	McNeil Consumer, Inc., Camp Hill Rd., Fort Washington, PA 19034.
60–809	Penicillin G Potassium Tablets USP, 100,000, 200,000, 250,000, 400,000, and 500,000 units.	Consolidated Pharmaceutical Group, 6110 Robinwood Rd., Baltimore, MD 21225.
60–855	Oxytetracycline HCl Capsules, 250 mg.	Rachelle Laboratories, Inc., 700 Henry Ford Ave., P.O. Box 2029, Long Beach, CA 90801.
60–869	Oxytetracycline HCl Capsule, 250 mg.	Proter S.p.A., c/o Arnold Buhl Christen, 1000 Connecticut Ave., Washington, DC 20086.
61–174	Candicidin.	Penick Corp., 1050 Wall St. West, Lyndhurst, NJ 07071.
61–396	Hetacillin Capsules.	Bristol-Myers, U.S. Pharmaceutical Group, Evansville, IN 47721–0001.
61–523	Tetracycline HCl Susceptibility Power, 20 mg.	Lederle Laboratories, Division of American Cyanamid Co., Pearl River, NY 10965.
61–676	Ampicillin Trihydrate Capsules, 250 mg and 500 mg.	Public Health Service, Health Service Administration, Perry Point, MD 21902.
61–700	Bacitracin Zinc USP for Compounding.	Alpharma A.S., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024.
61–718	Nystatin Vaginal Tablets USP, 100,000 units.	Holland-Rantos Co., Inc., 310 Enterprise Ave., Trenton, NJ 08638.
61–720	Doxycycline Oral Suspension USP.	Rachelle Laboratories, Inc.