

Any handicapped persons requiring special accommodations in order to attend the hearing should inform the contact person listed in order for FDA to be prepared to meet those needs.

To the extent that the conditions for the hearing as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h)

Dated: July 10, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-17535 Filed 7-17-95; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 95F-0174]

H.B. Fuller Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that H.B. Fuller Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of nonanoic acid, lactic acid, citric acid, sodium 1-octane sulfonate, tertiary butylhydroquinone, and the sodium salt of tetrapropylene-1,1-oxybis-benzenesulfonic acid as components of a sanitizing solution intended for general use on food-contact surfaces.

DATES: Written comments on the petitioner's environmental assessment by August 17, 1995.

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

FOR FURTHER INFORMATION CONTACT: Diane E. Robertson, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration,

200 C St. SW., Washington, DC 20204, 202-418-3089.

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 5B4462) has been filed by H.B. Fuller Co., c/o SRS International Corp., 1625 K St. NW., suite 1000, Washington, DC 20006-1604. The petition proposes to amend the food additive regulations in § 178.1010 *Sanitizing solutions* (21 CFR 178.1010) to provide for the safe use of nonanoic acid, lactic acid, citric acid, sodium 1-octane sulfonate, tertiary butylhydroquinone, and the sodium salt of tetrapropylene-1,1-oxybis-benzenesulfonic acid as components of a sanitizing solution intended for general use on food-contact surfaces.

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 August 17, 1995, 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: July 5, 1995.

Alan M. Rulis,

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

[FR Doc. 95-17639 Filed 7-17-95; 8:45 am]

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[Docket No. 95N-0206]

Richmar International, Inc., et al.; Withdrawal of Approval of 2 Abbreviated Antibiotic Applications and 15 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 2 abbreviated antibiotic applications (AADA's) and 15 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: AUGUST 17, 1995.

FOR FURTHER INFORMATION CONTACT: Lola E. Batson, Center for Drug Evaluation and Research (HFD-360), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1038.

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
AADA 60-446.	Tetracycline Oral Suspension, U.S.P	Richmar International, Inc., 1706 Birch Rd., McLean, VA 22101.
AADA 62-502.	Nystatin Vaginal Tablets, U.S.P., 100,000 units	Lemmon Co., 650 Cathill Rd., Sellersville, PA 18960.
ANDA 70-438.	Propranolol Hydrochloride Tablets, U.S.P., 10milligrams (mg) ..	Warner Chilcott, 201 Tabor Rd., Morris Plains, NJ 07950.
ANDA 70-439.	Propranolol Hydrochloride Tablets, U.S.P., 20 mg	Do.
ANDA 70-440.	Propranolol Hydrochloride Tablets, U.S.P., 40 mg	Do.
ANDA 70-441.	Propranolol Hydrochloride Tablets, U.S.P., 60 mg	Do.

Application No.	Drug	Applicant
ANDA 70-442.	Propranolol Hydrochloride Tablets, U.S.P., 80 mg	Do.
ANDA 72-289.	Sulfamethoxazole and Trimethoprim Oral Suspension, U.S.P., 200 mg/40 mg per 5 milliliters (mL).	Barre-National, Inc., 333 Cassell Dr., suite 3500, Baltimore, MD 21224.
ANDA 80-397.	Prednisone Tablets, U.S.P., 5 mg	Lemmon Co.
ANDA 80-398.	Prednisolone Tablets, U.S.P., 5 mg	Do.
ANDA 84-389.	Proprantheline Bromide Tablets, U.S.P., 15 mg	Do.
ANDA 86-490.	Chlordiazepoxide Hydrochloride Capsules, U.S.P., 10 mg	Do.
ANDA 86-769.	Lindane Lotion, U.S.P., 1%	Stiefel Laboratories, Inc., Route 145, Oak Hill, NY 12460.
ANDA 87-126.	Phentermine Hydrochloride Capsules, U.S.P., 30 mg (Brown/Clear).	Lemmon Co.
ANDA 87-777.	Phentermine Hydrochloride Capsules, U.S.P., 30 mg	Do.
ANDA 87-940.	Lindane Shampoo, U.S.P., 1%	Stiefel Laboratories, Inc.
ANDA 88-785.	Hydroxyzine Hydrochloride Syrup, U.S.P., 10 mg/5 mL	Barre-National, Inc.

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 above, and all amendments and supplements thereto, is hereby withdrawn, effective August 17, 1995.

Dated: July 5, 1995.

Murray M. Lumpkin,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 95-17641 Filed 7-17-95; 8:45 am]

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[Docket No. 95E-0089]

Determination of Regulatory Review Period for Purposes of Patent Extension; NAVELBINE® Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for NAVELBINE® Injection and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration,

rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was

issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product NAVELBINE® Injection (vinorelbine tartrate). NAVELBINE® Injection is indicated as a single agent or in combination with cisplatin for the first-line treatment in patients with unresectable, advanced nonsmall lung cancer. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for NAVELBINE® Injection (U.S. Patent No. 4,307,100) from Burroughs Wellcome Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 18, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of NAVELBINE® Injection represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for NAVELBINE® Injection is 1,621 days. Of this time, 1,137 days occurred during the testing phase of the regulatory review period, while 484 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug,*