Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. 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 include 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 generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On August 31, 2001, AAI International submitted a citizen petition (Docket No. 01P–0383/CP1) under 21 CFR 10.30 to FDA requesting that the agency determine whether azathioprine 25-mg tablet was withdrawn from sale for reasons of safety or effectiveness. Azathioprine 25-mg tablet is the subject of NDA 016–324. FDA approved NDA 016–324, currently held by Prometheus Laboratories, Inc. (Prometheus), on March 21, 1980. FDA has determined that azathioprine 25-mg tablet was withdrawn from sale.

FDA has reviewed its records and, under § 314.161, has determined that azathioprine 25-mg tablet was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list azathioprine 25-mg tablet in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to azathioprine 25-mg tablet may be approved by the agency.

Dated: February 11, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–4030 Filed 2–19–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0035]

Mylan Pharmaceuticals et al.; Withdrawal of Approval of 34 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 34 abbreviated new drug applications (ANDAs). 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.

DATES: Effective March 22, 2002.

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 request, waived their opportunity for a hearing.

ANDA No.	Drug	Applicant
61–530	Penicillin V Potassium Tablets USP, 250 milligrams (mg) and 500 mg.	Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310 Morgantown, WV 26504–4310.
61–829	Ampicillin for Oral Suspension USP, 125 mg/5 milliliters (mL) and 250mg/5 mL.	Do.
62–067	Amoxicillin Capsules USP, 250 mg and 500 mg	Do.
62–104	Neomycyin Sulfate with Hydrocortisone Ointment USP, 0.35% and 1%.	Clay-Park Laboratories, Inc., 1700 Bathgate Ave., Bronx, NY 10457.
62–280	Nystatin and Triamcinolone Acetonide Ointment USP	Do.
62–372	Mezlin (sterile mezlocillin sodium)	Bayer Corp. Pharmaceutical Division, 400 Morgan Lane, West Haven, CT 06516.
62–697	Mezlin (sterile mezlocillin sodium)	Do.
71–099	Bromatapp ER (brompheniramine maleate/phenylpropanolamine hydrochloride (HCl)) Extended-Release Tablets, 12 mg/75 mg.	Copley Pharmaceuticals, Inc., 25 John Rd. Canton, MA 02021.
71–551	Flurazepam HCl Capsules USP, 30 mg	Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207.
71–927	Flurazepam HCl Capsules USP, 15 mg	Do.
72–027	Fentanyl Citrate and Droperidol Injection	AstraZeneca LP, 1800 Concord Pike, P.O. Box 8355, Wilmington, DE 19803–8355.
72–070	Nalbuphine HCl Injection USP, 10 mg/mL	Do.
72–073	Nalbuphine HCl Injection USP, 20 mg/mL	Do.
72–921	Prazosin HCl Capsules USP, 2 mg	Purepac Pharmaceutical Co.
72–991	Prazosin HCl Capsules USP, 1 mg	Do.
72–992	Prazosin HCl Capsules USP, 5 mg	Do.
73–690	Calcitonin-Salmon Injection, 200 international units/mL	AstraZeneca LP.

ANDA No.	Drug	Applicant
74–579	Betamethasone Dipropionate Cream USP, 0.05% (base)	Clay-Park Laboratories, Inc.
75–263	Midazolam HCl Injection, 5 mg (base)/mL	AstraZeneca LP.
75–348	Ketorolac Tromethamine Injection USP, 15 mg/mL and 30 mg/mL.	Apothecon, Inc., P.O. Box 4500, Princeton, NJ 08543–4500.
75–355	Labetalol HCl Injection USP, 5 mg/mL	Do.
75–620	Midazolam HCl Injection, 1 mg (base)/mL and 5 mg (base)/mL.	Do.
75–641	Midazolam HCl Injection, 5 mg (base)/mL	Do.
75–642	Bisoprolol Fumarate and Hydrochlorothiazide Tablets	Do.
75–707	Famotidine Injection, 10 mg/mL	Do.
75–708	Famotidine Injection, 10 mg/mL (preservative free)	Do.
83–115	Niacin Tablets USP, 500 mg	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
84–968	Nitrofurazone Ointment USP, 0.2%	Clay-Park Laboratories, Inc.
85–130	Nitrofurazone Topical Solution USP, 0.2%	Do.
86–424	Triple Sulfa Vaginal Cream	Altana Inc., 60 Baylis Rd., Melville, NY 11747.
86–810	Fluocinolone Acetonide Cream USP, 0.01%	Clay-Park Laboratories, Inc.
86–811	Fluocinolone Acetonide Cream USP, 0.025%	Do.
89–784	Meperidine HCl Injection USP, 50 mg/mL	AstraZeneca LP.
89–788	Meperidine HCl Injection USP, 1,000 mg/mL	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 March 22, 2002.

Dated: February 12, 2002.

Steven K. Galson,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 02–4091 Filed 2–19–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0064]

Draft Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling.'' This draft guidance is neither final nor is it in effect at this time. Elsewhere in this issue of the **Federal Register**, the agency is proposing to classify encapsulated amalgam into class II, to amend the classification regulation for amalgam alloy to provide for special controls, and to reclassify dental mercury into class II. The draft guidance document is intended to serve as a special control for these devices.

DATES: Submit written or electronic comments on the draft guidance by May 21, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Susan Runner, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, the agency is proposing to classify encapsulated amalgam into class II, to amend the classification regulation for amalgam alloy to provide for special controls, and to reclassify dental mercury into class II. The draft guidance document is intended to serve as a special control for these devices. The guidance document contains recommendations concerning the content and format of labeling for these devices.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance document represents the agency's current thinking on encapsulated amalgam, amalgam alloy, and dental mercury labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations. This draft guidance document is issued as a level 1 guidance consistent with the GGP regulations.

III. Electronic Access

In order to receive the draft guidance entitled ''Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling '' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document