2008, and should submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 9, 2008.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Lee L. Zwanziger at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 18, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–9177 Filed 4–25–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0238]

Determination That TAPAZOLE Tablets and 18 Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that the 19 drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to the drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6308, Silver Spring, MD 20993–0002, 301–796–3601.

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. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (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 (the 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).

Under § 314.161(a) (21 CFR 314.161(a)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved or (2) whenever a listed drug is voluntarily withdrawn from sale, and ANDAs that refer to the listed drug have been approved. Section 314.161(d) provides that if FDA determines that a listed drug was removed from sale for safety or effectiveness reasons, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed. (As requested by the applicants, FDA withdrew approval of NDA 7–517 for TAPAZOLE Tablets in the **Federal Register** of November 7, 2007 (72 FR 62858), NDA 18–754 for ORUDIS Capsules in the **Federal Register** of June 16, 2006 (71 FR 34940), NDA 18–062 for PROVENTIL Syrup in the **Federal Register** of March 4, 2005 (70 FR 10651), and NDA 8–604 for PHENERGAN VC Syrup in the **Federal Register** of May 5, 2004 (69 FR 25124).

NDA No.	Drug	Applicant
7–517	TAPAZOLE (methimazole) Tablets, 5 milligrams (mg) and 10 mg	King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620
7–935	PHENERGAN (promethazine hydrochloride (HCl)) Tablets, 25 mg	Wyeth Pharmaceuticals,Inc., P.O. Box 8299, Philadelphia, PA 19101–8299
8–306	PHENERGAN with Codeine (codeine phosphate and promethazine HCl) Syrup, 6.25 mg/5 milliliters (mL), 10 mg/5 mL	ANI Pharmaceuticals, Inc., 7131 Ambassador Rd., Woodlawn, MD 21244

NDA No.	Drug	Applicant
8–306	PHENERGAN VC with Codeine (codeine phosphate; phenylephrine HCl; promethazine HCl) Syrup, 5 mg/5 mL; 6.25 mg/5 mL; 10 mg/5 mL	Do.
8–381	PHENERGAN FORTIS (promethazine HCl) Syrup, 25 mg/5 mL	Do.
8–381	PHENERGAN Plain (promethazine HCl) Syrup, 6.25 mg/5 mL	Do.
8–604	PHENERGAN VC (phenylephrine HCl; promethazine HCl) Syrup, 5 mg/5 mL; 6.25 mg/5 mL	Do.
9–000	CAFERGOT (caffeine; ergotamine tartrate) Suppository, 100 mg/2 mg	Novartis Pharmaceuticals Corp., One Health Plaza, East Hanover, NJ 07936–1080
9–509	ARAMINE (metaraminol bitartrate) Injection, equivalent to (EQ) 10 mg base/mL	Merck & Co., Inc., 770 Sumneytown Pike, BLA–20, P.O. Box 4, West Point, PA 19486
11–265	PHENERGAN with Dextromethorphan (dextromethorphan hydrobromide; promethazine HCl) Syrup, 6.25 mg/5 mL; 15 mg/5 mL	ANI
11–459	VISTARIL (hydroxyzine pamoate EQ hydroxyzine HCl) Capsules, 100 mg	Pfizer, Inc., 235 East 42nd St., New York, NY 10017
11–689	PHENERGAN (promethazine HCl) Suppository, 50 mg	Wyeth
12–125	CARBOCAINE (mepivacaine HCl) Injection, 3 % (30 mg/mL/1.8 mL cartridge)	Eastman Kodak Co., Dental Products, 343 State St., Rochester, NY 14612–1122
18–062	PROVENTIL (albuterol sulfate) Syrup, EQ 2 mg base/5mL	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033
18–152	ESKALITH CR (lithium carbonate) Extended Release Tablets, 450 mg	GlaxoSmithKline, One Franklin Plaza, P.O. Box 7929, Philadelphia, PA 19101–7929
18–200	MIDAMOR (amiloride HCl) Tablets, 5 mg	Merck
18–201	MODURETIC 5–50 (amiloride HCl; hydrochlorothiazide) Tablets, 5 mg/50 mg	Merck
18–754	ORUDIS (ketoprofen) Capsules, 25 mg, 50 mg, and 75 mg	Wyeth
20–460	CYTOVENE (ganciclovir) Capsules, 250 mg and 500 mg	Roche Laboratories, Inc., 340 Kingsland St., Nutley, NJ 07110–1199

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs for the products may also be approved by the agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: April 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–9161 Filed 4–25–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 73 FR 12742–12744 dated March 10, 2008).

This notice reflects organizational changes in the Health Resources and Services Administration. Specifically, this notice moves the Office of Management (RS) under the Immediate