DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0254]

Determination That THORAZINE (Chlorpromazine Hydrochloride) Injection and 18 Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that the 19 drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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 these 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 Pritzlaff, Center for Drug Evaluation and Research, 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 Under FDA regulations, a drug is withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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; (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved; and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, 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 20–225 for IMDUR (isosorbide mononitrate) Extended-Release Tablets in the **Federal Register** of February 11, 2009 (74 FR 6896) and NDA 11–556 for ANTURANE (sulfinpyrazone) Tablets and Capsules, NDA 15–500 for TOLINASE (tolazamide) Tablets, NDA 18–285 for VISKEN (pindolol) Tablets, NDA 20–137 for DEMADEX (torsemide) Injection, and NDA 20–154 for VIDEX (didanosine) Chewable Tablets in the **Federal Register** of May 19, 2009 (74 FR 23407)).

Application No.	Drug	Applicant
NDA 9–149	THORAZINE (chlorpromazine hydrochloride (HCl)) Injection, 25 milligrams (mg)/milliliter (mL)	GlaxoSmithKline, 2301 Renaissance Blvd., King of Prussia, PA 19406
NDA 9–149	THORAZINE (chlorpromazine HCl) Oral Concentrate, 30 mg/mL and 100 mg/mL	Do.
NDA 9–149	THORAZINE (chlorpromazine HCl) Oral Syrup, 10 mg/5 mL	Do.
NDA 9–149	THORAZINE (chlorpromazine) Suppositories, 25 mg and 100 mg	Do.
NDA 11–552	STELAZINE (trifluoperazine HCl) Tablets, Equivalent to (EQ) 1 mg base, EQ 2 mg base, EQ 5 mg base, and EQ 10 mg base	Do.
NDA 11–556	ANTURANE (sulfinpyrazone) Tablet, 100 mg	Novartis Pharmaceuticals Corp., One Health Plaza, East Hanover, NJ 07963
NDA 11–556	ANTURANE (sulfinpyrazone) Capsule, 200 mg	Do.
NDA 12–940	ISORDIL (isosorbide dinitrate) Sublingual Tablets, 2.5 mg, 5 mg, and 10 mg	Biovail Pharmaceuticals, Inc., 700 Route 202–206 North, Bridgewater, NJ 08807–0980
NDA 15–500	TOLINASE (tolazamide) Tablets, 100 mg, 250 mg, and 500 mg	Pfifzer, Inc., 235 East 42d St., New York, NY 10017

Application No.	Drug	Applicant
NDA 18–154	LONITEN (minoxidil) Tablets, 2.5 mg and 10 mg	Pharmacia & Upjohn Co., c/o Pfizer, Inc.
NDA 18–285	VISKEN (pindolol) Tablets, 5 mg and 10 mg	Novartis Pharmaceuticals Corp.
NDA 18–445	DOLOBID (diflunisal) Tablets, 250 mg and 500 mg	Merck & Co., Inc., Sunneytown Pike, P.O. Box 4, BLA–20, West Point, PA 19486
NDA 19–661	CYTOVENE IV (ganciclovir sodium) Injection, EQ 500 mg base/vial	Roche Laboratories, Inc., 340 Kingsland St., Nutley, NJ 07110–1199
NDA 20–027	CARDIZEM (diltiazem HCl) Injection, 5 mg/mL and 25 mg/vial	Biovail Pharmaecuticals, Inc.
NDA 20–137	DEMADEX (torsemide) Injection, 20 mg/2 mL (10 mg/mL) and 50 mg/5 mL (10 mg/mL)	Roche Laboratories, Inc.
NDA 20–154	VIDEX (didanosine) Chewable Tablets, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg	Bristol-Myers Squibb Co., P.O. Box 5100, Wallingford, CT 06492–7660
NDA 20–225	IMDUR (isosorbide mononitrate) Extended-Release Tablets, 30 mg, 60 mg, and 120 mg	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033
NDA 21–238	KYTRIL (granisetron HCl) Oral Solution, EQ 2 mg base/10 mL	Roche Laboratories, Inc.
NDA 21–301	LEVOXYL (levothyroxine sodium) Tablet, 0.3 mg	King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620

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 that refer to these 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: June 5, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of Federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Improved Antibodies Against ErbB4/Her4

Description of Technology: ErbB4/Her4 is a receptor tyrosine kinase that regulates cell proliferation, cell differentiation and cell survival. ErbB4 has been implicated in the pathology of numerous cancers (*e.g.,* breast cancer, non-small cell lung carcinoma, adenocarcinoma), as well as psychiatric disorders (*e.g.,* schizophrenia). As a result, ErbB4 is an excellent target for developing therapies against these diseases. Unfortunately, the study of ErbB4 has been slowed by the lack of highly specific and functional antibodies against the receptor.

In order to overcome the deficiencies with current ErbB4 antibodies, NIH inventors have generated three rabbit monoclonal antibodies with improved properties and versatility. Specifically, the mAb-6, mAb-7 and mAb-10 hybridomas produce antibodies with a high degree of specificity and affinity for ErbB4. These antibodies recognize specific epitopes on the intracellular domains of ErbB4 without cross-reaction against other proteins, and can be used successfully in the immunostaining of fixed tissue. Each antibody recognizes both human and mouse ErbB4, whereas only mAb-7 and mAb-10 recognize rat ErbB4.

Applications:

• Basic research tool for the study of ErbB4;