

Gamma-Dynacare Medical Laboratories,\* A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519-679-1630.

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713-856-8288/800-800-2387.

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908-526-2400/800-437-4986. (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919-572-6900/800-833-3984. (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866-827-8042/800-233-6339. (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913-888-3927/800-873-8845. (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)

Maxxam Analytics,\* 6740 Campobello Road, Mississauga, ON, Canada L5N 2L8, 905-817-5700. (Formerly: Maxxam Analytics Inc., NOVAMANN (Ontario), Inc.)

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651-636-7466/800-832-3244.

MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503-413-5295/800-950-5295.

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612-725-2088.

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661-322-4250/800-350-3515.

One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888-747-3774. (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory)

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800-328-6942. (Formerly: Centinela

Hospital Airport Toxicology Laboratory)

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509-755-8991/800-541-7891x7.

Phamatech, Inc., 10151 Barnes Canyon Road, San Diego, CA 92121, 858-643-5555.

Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800-729-6432. (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610-631-4600/877-642-2216. (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 8401 Fallbrook Ave., West Hills, CA 91304, 800-877-2520. (Formerly: SmithKline Beecham Clinical Laboratories)

S.E.D. Medical Laboratories, 5601 Office Blvd., Albuquerque, NM 87109, 505-727-6300/800-999-5227.

South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 574-234-4176 x1276.

Southwest Laboratories, 4625 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602-438-8507/800-279-0027.

St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St., Oklahoma City, OK 73101, 405-272-7052.

STERLING Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421, 800-442-0438.

Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, Suite 208, Columbia, MO 65203, 573-882-1273.

Toxicology Testing Service, Inc., 5426 N.W. 79th Ave., Miami, FL 33166, 305-593-2260.

US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755-5235, 301-677-7085.

\* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active

role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 13, 2004 (69 FR 19644). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Dated: June 25, 2010.

**Dennis O. Romero,**

*Deputy Executive Officer and Deputy Director, Office of Program Services.*

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**BILLING CODE 4160-20-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-P-0171]

#### Determination That ACCUTANE (Isotretinoin) Capsules, 10 Milligrams, 20 Milligrams, and 40 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) is announcing its determination that ACCUTANE (isotretinoin) Capsules, 10 milligrams (mg), 20 mg, and 40 mg, 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 product 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, 301-796-3506.

**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 applicants 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. ANDA applicants 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 (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 known generally as the "Orange Book." Under FDA regulations, drugs are removed 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)(1) (21 CFR 314.161(a)(1)), the agency must determine 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. FDA may not approve an ANDA that does not refer to a listed drug.

ACCUTANE (isotretinoin) Capsules, 10 mg, 20 mg, and 40 mg, are the subject of NDA 18-662, held by Hoffman-La Roche, Inc. (Roche), and initially approved on May 7, 1982. ACCUTANE is indicated for the treatment of severe recalcitrant nodular acne. In a letter dated June 24, 2009, Roche notified FDA that ACCUTANE (isotretinoin) Capsules, 10 mg, 20 mg, and 40 mg, were being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book. There are three approved ANDAs for isotretinoin capsules; these are listed in the Orange Book and, following the discontinuation of ACCUTANE, one of them was designated as the listed drug to which new ANDAs should refer.

Sun Pharmaceutical Industries, Inc., submitted a citizen petition dated March 22, 2010 (Docket No. FDA-2010-P-0171), under 21 CFR 10.30, requesting that the agency determine whether ACCUTANE (isotretinoin)

Capsules, 10 mg, 20 mg, and 40 mg, were withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and, under § 314.161, has determined that ACCUTANE (isotretinoin) Capsules, 10 mg, 20 mg, and 40 mg, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that ACCUTANE (isotretinoin) Capsules, 10 mg, 20 mg, and 40 mg, were withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ACCUTANE (isotretinoin) Capsules, 10 mg, 20 mg, and 40 mg, 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.

FDA will not begin procedures to withdraw approval of approved ANDAs that refer to ACCUTANE. Additional ANDAs for isotretinoin capsules may also be approved by the agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for isotretinoin capsules should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: June 30, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2010-P-0027, FDA-2010-P-0059, and FDA-2010-P-0051]

#### **Determination That ACTONEL (Risendronate Sodium) Tablets, 75 Milligrams, and ACTONEL WITH CALCIUM (Risendronate Sodium and Calcium Carbonate (Copackaged)) Tablets, 35 Milligrams/500 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) is announcing the determination that ACTONEL (risendronate sodium) Tablets, 75 milligrams (mg), and ACTONEL WITH CALCIUM (risendronate sodium and calcium carbonate (copackaged)) Tablets, 35 mg/500 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for these products, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** Jane Baluss, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6362, Silver Spring, MD 20993-0002, 301-796-3469.

**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 applicants 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. ANDA applicants 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 (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 known generally as the "Orange Book." Under FDA regulations, drugs are removed 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)(1) (21 CFR 314.161(a)(1)), the agency must determine 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. FDA may not approve an