

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.

U.S. 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: September 8, 2010.

**Elaine Parry,**

*Director, Office of Management, Technology, and Operations, SAMHSA.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-P-0157]

#### Determination That VESANOID (Tretinoin) Capsules, 10 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) has determined that VESANOID (tretinoin) Capsules, 10 milligrams (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 the abbreviated new drug application (ANDA) that refers to this drug product, 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:** Molly Flannery, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6237, Silver Spring, MD 20993-0002, 301-796-3543.

**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.

VESANOID (tretinoin) Capsules, 10 mg, are the subject of NDA 20-438, held by Hoffman-La Roche Inc. (Roche), and initially approved on November 22, 1995. VESANOID is indicated for the "induction of remission in patients with acute promyelocytic leukemia (APL), French-American-British (FAB) classification M3 (including the M3 variant), characterized by the presence of the t(15;17) translocation and/or the presence of the PML/RAR $\alpha$  [promyelocytic leukemia/retinoic acid receptor alpha] gene who are refractory to, or who have relapsed from, anthracycline chemotherapy, or for whom anthracycline-based chemotherapy is contraindicated" (VESANOID labeling).

In a letter dated December 2, 2009, Roche notified FDA that VESANOID (tretinoin) Capsules, 10 mg, were being discontinued, and FDA moved the drug product to the "Discontinued Drug

Product List" section of the Orange Book. There is one approved ANDA for tretinoin capsules, 10 mg (ANDA No. 77-684); this drug product is listed in the Orange Book and, following the discontinuation of VESANOID, was designated as the reference listed drug to which new ANDAs should refer.

Rakoczy Molino Mazzochi Siwik LLP submitted a citizen petition dated March 17, 2010 (Docket No. FDA-2010-P-0157), under 21 CFR 10.30, requesting that the agency determine whether VESANOID (tretinoin) Capsules, 10 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA has determined under § 314.161 that VESANOID (tretinoin) Capsules, 10 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that VESANOID (tretinoin) Capsules, 10 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of VESANOID (tretinoin) Capsules, 10 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events and have 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 VESANOID (tretinoin) Capsules, 10 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 the approved ANDA that refers to VESANOID. Additional ANDAs for tretinoin capsules, 10 mg, may also be approved by the agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: September 8, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-D-0462]

#### Draft Guidance for Industry on Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Agents for Treatment; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Agents for Treatment." The purpose of this guidance is to assist sponsors in all phases of development of direct-acting antiviral agents (DAAs), defined as agents that interfere with specific steps in the hepatitis C virus (HCV) replication cycle. The guidance outlines the types of nonclinical studies and clinical trials recommended throughout the drug development process to support approval of treatments for chronic hepatitis C (CHC), including in patients with compensated and decompensated cirrhosis and those co-infected with human immunodeficiency virus (HIV). The guidance also addresses pre-approval access in the form of treatment investigational new drug applications (INDs) and intermediate-sized safety protocols.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 15, 2010.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.