

response to PAR 06-057, "Agricultural Center Review."

*For Further Information Contact:* Stephen Olenchock, Scientific Review Administrator, 1095 Willowdale Road, Morgantown, WV 26506, telephone (304) 285-6271.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2001D-0432]

#### Guidance for Industry on Orally Inhaled and Intranasal Corticosteroids: Evaluation of the Effects on Growth in Children; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Orally Inhaled and Intranasal Corticosteroids: Evaluation of the Effects on Growth in Children." This guidance provides recommendations regarding the design, conduct, and evaluation of clinical trials to assess the effects of orally inhaled and intranasal corticosteroids on growth in children. For this class of drug products, measurement of growth is considered a sensitive surrogate of, and an important sentinel for, the potential to cause systemic effects. Growth studies designed and carried out following the recommendations in this guidance can provide adequate and well-controlled data that are consistent among drug products and can be included in product labeling. This guidance finalizes the draft guidance published on November 6, 2001.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane,

Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Peter Starke, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3300, Silver Spring, MD 20993-0002, 301-796-2300.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled "Orally Inhaled and Intranasal Corticosteroids: Evaluation of the Effects on Growth in Children." This guidance provides recommendations for the design, conduct, and evaluation of clinical studies to assess the effects of orally inhaled and intranasal corticosteroids on linear growth ("growth study"). The guidance was developed by the Division of Pulmonary and Allergy Products in consultation with the Division of Metabolism and Endocrinology Products and the Office of Biostatistics to encourage the collection of evidence that can consistently and accurately describe the effects of intranasal and orally inhaled corticosteroids on growth velocity in children.

In July 1998, the Pulmonary and Allergy Drugs Advisory Committee and the Metabolic and Endocrine Drugs Advisory Committee were jointly convened to discuss the implications of findings in previous clinical studies that indicated that inhaled corticosteroids can, as a class of drug products, affect linear growth in pediatric patients. The joint committee concluded that data were sufficient to justify inclusion of a precautionary statement in the labeling for this class of drug products, but the data were inadequate to precisely determine the decrement in growth velocity resulting from the use of these drug products. Members of the joint committee recommended that companies filing new drug applications for all newly approved corticosteroid products conduct further studies, as post-approval phase 4 commitments, to assess the effects of nasally and orally inhaled corticosteroids on growth velocity in prepubertal children. On November 6, 2001 (66 FR 56109), FDA

published for comment in the **Federal Register** a draft of this guidance.

Comments received from industry, professional societies, and consumer groups on the draft guidance have been taken into consideration in finalizing this guidance. Changes are based on thorough review of all comments received, growth studies submitted since publication of the draft guidance, and previously submitted growth data. Changes or updates were made to all sections of the guidance, and are briefly summarized here.

A new overview section and updated background and data analysis sections include a more thorough discussion of the objective of and the appropriate statistical comparisons for a growth study. These changes will affect future labeling for such studies. Recommendations for sample size calculations and primary and secondary "sensitivity" analyses have been reviewed and modified based on review of growth studies submitted since publication of the draft guidance as well as previously submitted data. The general study recommendations and protocol design sections include a discussion of the appropriate patient populations to be studied and modifications to recommendations for the inclusion and exclusion criteria, assessments of adherence, and spacer use.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on the evaluation of the effects of orally inhaled and intranasal corticosteroids on growth in children. 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 requirements of the applicable statutes and regulations.

##### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: February 26, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.  
**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at <http://workplace.samhsa.gov> and <http://www.drugfreeworkplace.gov>.

**FOR FURTHER INFORMATION CONTACT:** Mrs. Giselle Hersch or Dr. Walter Vogl, Division of Workplace Programs, SAMHSA/CSAP, Room 2-1035, 1 Choke Cherry Road, Rockville, Maryland 20857; 240-276-2600 (voice), 240-276-2610 (fax).

**SUPPLEMENTARY INFORMATION:** The Mandatory Guidelines were developed

in accordance with Executive Order 12564 and section 503 of Pub. L. 100-71. Subpart C of the Mandatory Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A laboratory must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Mandatory Guidelines dated April 13, 2004 (69 FR 19644), the following laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414-328-7840 / 800-877-7016 (Formerly: Bayshore Clinical Laboratory)

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585-429-2264.

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901-794-5770 / 888-290-1150.

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615-255-2400.

Baptist Medical Center—Toxicology Laboratory, 9601 I-630, Exit 7, Little Rock, AR 72205-7299, 501-202-2783 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215-2802, 800-445-6917.

Diagnostic Services, Inc., dba DSI, 12700 Westlinks Drive, Fort Myers, FL 33913, 239-561-8200 / 800-735-5416.

Doctors Laboratory, Inc., 2906 Julia Drive, Valdosta, GA 31602, 229-671-2281.

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Road, Warminster, PA 18974, 215-674-9310.

Dynacare Kasper Medical Laboratories,\* 10150-102 St., Suite 200, Edmonton, Alberta, Canada T5J 5E2, 780-451-3702 / 800-661-9876.

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662-236-2609.

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

Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504-361-8989/800-433-3823 (Formerly: Laboratory Specialists, Inc.)

Kroll Scientific Testing Laboratories, Inc., 450 Southlake Blvd., Richmond, VA 23236, 804-378-9130 (Formerly: Scientific Testing Laboratories, Inc.)

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, 10788 Roselle St., San Diego, CA 92121, 800-882-7272 (Formerly: Poisonlab, Inc)

Laboratory Corporation of America Holdings, 550 17th Ave., Suite 300, Seattle, WA 98122, 206-923-7020/800-898-0180 (Formerly: DrugProof, Division of Dynacare/Laboratory of Pathology, LLC; Laboratory of Pathology of Seattle, Inc.; DrugProof, Division of Laboratory of Pathology of Seattle, Inc.)

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.)

Marshfield Laboratories, Forensic Toxicology Laboratory, 1000 North Oak Ave., Marshfield, WI 54449, 715-389-3734/800-331-3734.