

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Medical Device Classification Product Codes.” The purpose of the guidance document is to educate regulated industry and FDA Staff on how, when, and why to use classification product codes for medical devices regulated by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). This document describes how classification product codes are used in a variety of FDA program areas to regulate and track medical devices. This draft guidance is not final nor is it in effect at this time.

**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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 2, 2012.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled “Medical Device Classification Product Codes” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002 or Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at (301) 847-8149. The draft guidance may also be obtained by mail by calling CBER at (800) 835-4709 or (301) 827-1800. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to 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. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Diane Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 66, Rm. 1644, Silver Spring, MD 20993-0002, (301) 796-6559; and

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, (301) 827-6210.

### I. Background

Since the May 28, 1976, Medical Device Amendments were passed, the Classification Regulation Panels (parts 862 through 892 (21 CFR parts 862 through 892)) have been the basis for the CDRH’s Classification Product Code structure and organization. These 16 Panels have largely been the driving force for CDRH’s internal organizational structure as well. Relying on the Classification Regulation Panels structure, CDRH created classification product codes to assist in accurate identification and tracking of current medical devices and to allow for tracking and easy reference of predicate device types.

Classification product codes are a method of classifying medical devices. Medical device product codes consist of a three-letter combination, which associates a device’s type with a product classification. Classification product codes and information associated with these devices, such as names and attributes, are assigned by CDRH to support their regulation.

The purpose of the guidance document is to educate regulated industry and FDA Staff on how, when, and why to use classification product codes for medical devices in a variety of FDA program areas to regulate and track medical devices. This document is limited to medical devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) and does not discuss classification products codes used to regulate non-medical electronic radiation emitting products.

The scope of the guidance document includes devices described in the existing classification under parts 862 through 892. It also describes how classification product codes are used for CBER regulated devices, which currently do not fall within this existing classification. This guidance may also be applicable to future devices. It also covers unclassified devices and devices not yet classified.

### II. Significance of Guidance

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking

on medical device classification product codes. 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 statute and regulations.

### III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or from the CBER Internet site at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. To receive “Medical Device Classification Product Codes,” you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to (301) 847-8149 to receive a hard copy. Please use the document number 1774 to identify the guidance you are requesting.

### IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 28, 2011.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

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**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Current List of Laboratories and Instrumented Initial Testing Facilities 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 and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards 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); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); and on April 30, 2010 (75 FR 22809).

A notice listing all currently certified Laboratories and Instrumented Initial Testing Facilities (IITF) is published in the **Federal Register** during the first week of each month. If any Laboratory/IITF's certification is suspended or revoked, the Laboratory/IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any Laboratory/IITF 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://www.workplace.samhsa.gov> and <http://www.drugfreeworkplace.gov>.

**FOR FURTHER INFORMATION CONTACT:** Mrs. Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 2-1042, One Choke Cherry Road, Rockville, Maryland 20857; (240) 276-2600 (voice), (240) 276-2610 (fax).

**SUPPLEMENTARY INFORMATION:** The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100-71. The "Mandatory Guidelines for Federal Workplace Drug Testing Programs", as amended in the revisions listed above, requires {or set} strict standards that Laboratories and Instrumented Initial Testing Facilities (IITF) must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies.

To become certified, an applicant Laboratory/IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a Laboratory/IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and Instrumented Initial Testing Facilities (IITF) in the applicant stage of certification are not to be

considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A Laboratory/IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with the Mandatory Guidelines dated November 25, 2008 (73 FR 71858), the following Laboratories and Instrumented Initial Testing Facilities (IITF) meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

#### **Instrumented Initial Testing Facilities (IITF)**

None.

#### **Laboratories**

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, 345 Hill Ave., Nashville, TN 37210, (615) 255-2400, (Formerly: Aegis Sciences Corporation, Aegis Analytical Laboratories, Inc.).

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

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, (804) 378-9130, (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.).

Baptist Medical Center-Toxicology Laboratory, 11401 I-30, Little Rock, AR 72209-7056, (501) 202-2783, (Formerly: Forensic Toxicology Laboratory Baptist Medical Center) Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215-2802, (800) 445-6917.

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.

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.

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 NW. 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 30, 2010 (75 FR 22809). 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: December 22, 2011.

**Janine Denis Cook,**

*Chemist, Division of Workplace Programs, Center for Substance Abuse Prevention, SAMHSA.*

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**BILLING CODE 4162-20-P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Citizenship and Immigration Services

#### Agency Information Collection Activities: Form N-600, Revision of a Currently Approved Information Collection; Comment Request

**ACTION:** 30-Day Notice of Information Collection Under Review: Form N-600, Application for Certificate of Citizenship.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on September 27, 2011, at 76 FR 59710, allowing for a 60-day public comment period. USCIS received comments for this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until February 2, 2012. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this

notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), and to the Office of Management and Budget (OMB) USCIS Desk Officer. Comments may be submitted to: USCIS, Chief, Regulatory Products Division, 20 Massachusetts Avenue, Washington, DC 20529-2020. Comments may also be submitted to DHS via facsimile to (202) 272-0997 or via email at [uscisfrcomment@dhs.gov](mailto:uscisfrcomment@dhs.gov), and to the OMB USCIS Desk Officer via facsimile at (202) 395-5806 or via email at [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). When submitting comments by email please make sure to add OMB Control Number 1615-0057 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

#### *Overview of this information collection:*

(1) *Type of Information Collection:* Revision of a currently approved information collection.

(2) *Title of the Form/Collection:* Application for Certificate of Citizenship.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form N-600; U.S. Citizenship and Immigration Services (USCIS).

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Individuals or Households.* USCIS uses the information on Form N-600 to make a determination that the citizenship eligibility requirements and conditions are met by the applicant.