ANNUALIZED SUMMARY TABLE

Respondents	Number of respondents	Total responses	Total annualized hour burden per respondent *
Adolescent	200	2000	7.25
Collateral	200	5000	4.1
Project Coordinator	4	1204	65.25
Telephone Support Volunteer	8	7608	345.75
Social Network Site Moderator	1	53	26.25
Family Program Clinician	4	5604	278.75
Support Services Supervisor	1	37	30.25
Total	418	21,506	757.6

* Total Annualized Hour Burden per Respondent = Responses per Respondent × Hours per.

Written comments and recommendations concerning the proposed information collection should be sent by December 7, 2009 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–5806.

Dated: October 30, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–26803 Filed 11–5–09; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0319]

Guidance for Industry and Food and Drug Administration Staff; In Vitro Diagnostic 2009 H1N1 Tests for Use in the 2009 H1N1 Emergency; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''In Vitro Diagnostic 2009 H1N1 Tests for Use in the 2009 H1N1 Emergency.'' FDA is issuing this guidance to inform industry and agency staff of its recommendations for the type of information and data FDA believes needs to be included in an Emergency Use Authorization Request (EUA) for in vitro diagnostic (IVD) devices intended for use in diagnosing 2009 H1N1 Influenza virus infections during the emergency involving Swine Influenza A[1]. The Secretary of the Department of Health and Human Services (HHS) declared the emergency on April 26, 2009, in accordance with the Federal Food, Drug, and Cosmetics Act (the Act).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidelines are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''In Vitro Diagnostic 2009 H1N1 Tests for Use in the 2009 H1N1 Emergency'' 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. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sally Hojvat, Center for Devices and Radiological Health WO/66, rm. 5552, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–5455.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document provides recommendations on the types of information and data that FDA believes needs to be included in an Emergency Use Authorization Request (EUA) for in vitro diagnostic (IVD) devices intended for use in diagnosing 2009 H1N1 Influenza virus infections during the emergency involving Swine Influenza A. While FDA encourages the submission of premarket notifications (510(k)s) for all 2009 H1N1 tests, the agency is aware that during a declared emergency, it may not be possible for manufacturers of 2009 H1N1 tests to submit a 510(k) prior to distributing or offering a test. For example, during the initial phase of the emergency, positive clinical specimens may not be readily available for use in device evaluations. The identification of acute test capacity need may limit the ability to test the usual number of specimens needed for a 510(k). Additionally, appropriate validation specimens may not be available in certain areas at the time the test is needed. If manufacturers of 2009 H1N1 tests are unable to submit a premarket notification and there is a continued public health need for 2009 H1N1 tests during this declared emergency, manufacturers should submit an EUA request to FDA. Public participation is not feasible or appropriate since the agency must act immediately to protect the public health during the declared emergency concerning 2009 H1N1 Influenza. This guidance applies to 2009 H1N1 tests during the time that the declaration of emergency concerning 2009 H1N1 Influenza is in effect.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on *in vitro diagnostic 2009 H1N1 tests for use in the 2009 H1N1 emergency*. It does not create or confer any rights for or on any person and does not operate to bind FDA or the

[1] Swine Influenza A is now known as 2009 H1N1 Influenza (2009 H1N1).

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 guidance may do so by using the Internet. To receive ''*In Vitro Diagnostic 2009 H1N1 Tests for Use in the 2009 H1N1 Emergency*,'' you may either send an e-mail request to *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 1706 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available at *http://www.regulations.gov*.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814 have been approved under OMB Control No. 0910–0231; the collections of information in 21 CFR part 807 Subpart E have been approved under OMB Control No. 0910–0120; the collections of information in 21 U.S.C. 360bbb–3(b) have been approved under OMB Control No. 0910–0584; the collections of information in 21 CFR part 812 have been approved under OMB Control No. 0910–0078; the collections in 21 CFR 493.17 have been approved under OMB Control No. 0910–0607; the collections of information in 21 CFR part 56 have been approved under OMB Control No. 0910–0130; the collections of information in Section 564(b)(1) of the FD&C Act have been approved under OMB Control No. 0910–0595; the collections of information in 21 CFR part 820 have been approved under OMB Control No. 0910–0073; and the collections of information in 21 CFR 809.10 have been approved under OMB Control No. 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 2, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–26737 Filed 11–5–09; 8:45 am]

BILLING CODE 4160–01–S

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://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 developed in accordance with Executive Order 12564 and section 503 of Public Law 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, 345 Hill Ave., Nashville, TN 37210, 615–255–2400, (Formerly: Aegis Sciences Corporation, Aegis Analytical Laboratories, Inc.).

Baptist Medical Center-Toxicology Laboratory, 9601 I–630, Exit 7, Little