Dated: September 5, 2007.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E7–18116 Filed 9–13–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10236 and CMS–10079]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Disclosure of Financial Relationships Report (''DFRR''); *Form Number:* CMS–10236 (OMB#: 0938–New); *Use:* Section 1877(f) of the Social Security Act requires that each entity providing covered items or services for which payment may be made shall provide the Secretary with information concerning the entity's ownership, investment, and compensation arrangements, in such form, manner, and at such times as the Secretary shall specify. DFRR is a new collection instrument that will be used by CMS to obtain information necessary to analyze each hospital's compliance with section 1877 of the Social Security Act (''the physician self-referral law''), and implementing regulations (42 Code of Federal Regulations, Subpart J). Based upon public comments and CMS review, a number of changes were made to the DFRR. The most significant change to the DFRR involves the addition of worksheets to capture information concerning indirect ownership. Refer to the ''Summary of Changes to the Disclosure of Financial Relationships Report (DFRR)'' document to view a list of changes. *Frequency:* Reporting—Once; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 3,000.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Hospital Wage Index Occupational Mix Survey and Supporting Regulations in 42 CFR, section 412.64; *Use:* Section 304(c) of Public Law 106–554 mandates an occupational mix adjustment to the wage index, requiring the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. The 2007/2008 revised survey will provide for the collection of hospital-specific wages and hours data for a 1-year prospective reporting period (July 1, 2007 through June 30, 2008), additional clarifications to the survey instructions, the elimination of the RN subcategories, some refinements to the definitions for the occupational categories, and the inclusion of additional cost centers that typically provide nursing services. Additional revisions include expanding the current cost center list to include cost center 57—Renal Dialysis. For more details, please refer to the ''Medicare Wage Index Occupational Mix Survey—Summary of Changes'' document.

The 2007/2008 Medicare occupational mix survey will be applied beginning with the FY 2010 wage index. Each of the approximately 3,600 inpatient prospective payment system providers participating in the Medicare program will be required to complete the revised Medicare Wage Index Occupational Mix Survey. The revised survey will be forwarded to hospitals through CMS's fiscal intermediaries and will be made available on CMS's Web site. *Form Number:* CMS–10079 (OMB#: 0938–0907); *Frequency:* Reporting: Yearly, biennially and occasionally; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 3,600; *Total Annual Responses:* 3,600; *Total Annual Hours:* 1,728,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: September 6, 2007.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E7–18117 Filed 9–13–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0336]

Guidance for Industry and Food and Drug Administration Staff; Commercially Distributed Analyte Specific Reagents: Frequently Asked Questions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions.'' FDA is issuing this guidance to clarify the regulations regarding commercially distributed ASRs and the role and responsibilities of ASR manufacturers. The draft of this guidance was issued September 7, 2006.

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

Manufacturers should ensure their Class II or Class III in vitro diagnostic devices, that are currently inappropriately labeled and marketed as ASRs, comply with the law by September 15, 2008.

ADDRESSES: Submit written requests for single copies of the guidance document

entitled ''Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850 or to the Office of Communication, Training, and Manufacturers Assistance (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 request, or fax your request to 240–276–3151. 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 either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Courtney Harper, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0694.

For further information concerning the guidance as it related to devices regulated by CBER: Martin Ruta, Center for Biologics Evaluation and Research (HFM–300), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3518.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is providing this guidance in order to minimize confusion regarding particular marketing practices pertaining to ASRs. The guidance is not intended to cover the role of clinical laboratories in the development of laboratory developed tests. As noted in this guidance document, ASRs are building blocks of laboratory developed tests. With this final guidance document, FDA seeks to advise ASR manufacturers that it views certain practices as being inconsistent with the marketing of an ASR, as defined under § 864.4020 (21 CFR 864.4020). Some manufacturers have believed that when they combine a Class I ASR, which is exempt from premarket notification requirements under section 510(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)), with other products, or with instructions for use in a specific test, the product may still be regarded as an ASR that retains class I exempt status because the product contains an ASR. However, as explained in this guidance, when an ASR is marketed in combination with other products, with instructions for use, or with specific claims, FDA views the product as no longer being an ASR within the meaning of § 864.4020. Instead, FDA views products marketed in this way as another type of in vitro diagnostic device (IVD) or device component not covered by the ASR regulations and, therefore, not necessarily exempt from premarket notification.

The draft of this guidance was published in the **Federal Register** of September 7, 2006 (71 FR 52799). FDA received and considered more than 30 sets of comments on the draft guidance document. After taking the comments into consideration, FDA has revised the draft document to provide clarifications as needed. This includes clarifying that FDA views ASRs as being intended to detect a single ligand or target. This guidance further clarifies that oligonucleotide primer pairs and polyclonal antibodies can meet the definition of an ASR when properly marketed because they are for the identification of a single target or ligand (e.g., used to detect a single protein, a single nucleotide change, a single epitope). In addition, FDA has clarified that where manufacturers provide laboratories with information describing the use of their product in a specific test, the manufacturer's product would fall outside the definition of an ASR.

In order to assist manufacturers of Class II or III IVDs that are currently being inappropriately labeled and marketed as ASRs to come into regulatory compliance, FDA intends to exercise enforcement discretion with respect to premarket approval and clearance requirements for 12 months (see **DATES**). Manufacturers should ensure their products comply with the law by (see **DATES**).

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 commercially distributed ASRs. 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 guidance may do so by using the Internet. To receive ''Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions,'' 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 240–276–3151 to receive a hard copy. Please use the document number 1590 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 on the CBER Internet site at *http://www.fda.gov/cber/guidelines.htm* or on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. 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 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR 809.10 and 809.30 (§ 809.30) have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR 807.22 and 807.31(e) are approved under OMB control number 0910–0387; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR

814.20 have been approved under OMB control number 0910–0231.

In addition, the labeling for Class I, exempt ASRs must bear the statement, ''Analyte Specific Reagent. Analytical and performance characteristics are not established.'' Class II or III ASRs must bear the statement, ''Analyte Specific Reagent. Except as a component of the approved/cleared test (name of approved/cleared test), analytical and performance characteristics are not established'' (§ 809.30(d)(2) and (d)(3)). The disclaimer and these statements do not constitute ''collections of information'' under the PRA. Rather, they are ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

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: September 10, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–18108 Filed 9–13–07; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5100–FA–13]

Announcement of Funding Awards for Fiscal Year 2007; Hispanic-Serving Institutions Assisting Communities Program

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with section 102 (a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this document notifies the public of funding awards for Fiscal Year 2007 Hispanic-Serving Institutions Assisting Communities Program (HSIAC). The purpose of this document is to announce the names, addresses and the amount awarded to the winners to be used to help Hispanic-Serving Institutions of Higher Education to expand their role and effectiveness in addressing community development needs in their localities, consistent with the purposes of Title I of the Housing and Community Development Act of 1974 as amended.

FOR FURTHER INFORMATION CONTACT: Susan Brunson, Office of University Partnerships, U.S. Department of Housing and Urban Development, Room 8106, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 402–3852. To provide service for persons who are hearing-or-speech-impaired, this number may be reached via TTY by Dialing the Federal Information Relay Service on (800) 877–8339 or (202) 708–1455. (Telephone numbers, other than ''800'' TTY numbers, are not toll free).

SUPPLEMENTARY INFORMATION: The Hispanic-Serving Institutions Assisting Communities Program was approved by Congress under the Revised Continuing Appropriations Resolution, 2007 and is administered by the Office of University Partnerships under the Assistant Secretary for Policy Development and Research. In addition to this program, the Office of University Partnerships administers HUD's ongoing grant programs to institutions of higher education as well as creates initiatives through which colleges and universities can bring their traditional missions of teaching, research, service, and outreach to bear on the pressing local problems in their communities.

The HSIAC program provides funds for a wide range of CDBG-eligible activities including housing rehabilitation and financing, property demolition or acquisition, public facilities, economic development, business entrepreneurship, and fair housing programs.

The Catalog of Federal Domestic Assistance number for this program is 14.514.

On March 13, 2007, (FR Vol. 72, No. 48, 11477), HUD published a Notice of Funding Availability approximately $5.9 million in Fiscal Year 2007, plus $111,226 in unobligated funds for the HSIAC Program.

The Department reviewed, evaluated, and scored the applications received based on the criteria in the NOFA. As a result, HUD has funded the applications below, in accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat. 1987, 42 U.S.C. 3545).

List of Awardees for Grant Assistance Under the FY 2007 Hispanic-Serving Institutions Assisting Communities Program Funding Competition, by Institution, Address and Grant Amount

Region VI

1. San Antonio College, Dr. Helen Vera, San Antonio College, 1300 San Pedro Ave., San Antonio, TX 78212–4299. Grant: $597,530.

2. Midland College, Mr. Alfredo Chaparro, Midland College, 3600 North Garfield, Midland, TX 79705. Grant: $600,000.

Region VIII

3. Otero Junior College, Mr. Gary Ashida, Otero Junior College, 1802 Colorado Ave., La Junta, CO 81050. Grant: $599,176.

4. SBCCOES dba Trinidad State Junior College, Ms. Kerry Gabrielson, SBCCOES dba Trinidad State Junior College, 600 Prospect Street, Trinidad, CO 81082. Grant: $599,067.

Region IX

5. Los Angeles Trade-Technical College, Dr. Denise Fairchild, Los Angeles Trade-Technical College, 400 West Washington Blvd., Los Angeles, CA 90015–4181. Grant: $599,979.

6. Los Angeles Valley College, Dr. Deborah diCesare, Los Angeles Valley College, 5800 Fulton Ave., Valley Glen, CA 91401–4096. Grant: $600,000.

7. California State University-Long Beach Foundation, Ms. Denise Bell, California State University-Long Beach Foundation, 6300 State University Drive, Suite 332, Long Beach, CA 90815. Grant: $599,885.

8. Foundation of California State University Monterey Bay, Ms. Patricia Casey, Foundation of California State University Monterey Bay, 100 Campus Center, Bldg. 97, Seaside, CA 93955. Grant: $599,880.

9. Central Arizona-Pinal County Community College District, Mr. Al Larson, Central Arizona-Pinal County Community College District, 8470 North Overfield Road, Coolidge, AZ 85228. Grant: $599,985.

Region X

10. Heritage University, Mr. Rick Gagnier, Heritage University, 3240 Fort Road, Toppenish, WA 98948. Grant: $600,000.

Dated: September 7, 2007.

Darlene F. Williams,

Assistant Secretary for Policy Development and Research.

[FR Doc. E7–18119 Filed 9–13–07; 8:45 am]

BILLING CODE 4210–67–P