

In row 1 of table 1 we estimate the total annual hourly burden necessary to comply with the requirement under section 403(y) of the FD&C Act to be 1,112 hours. Using historical A.C. Nielson Sales Scanner Data, we estimate the number of dietary supplement stock keeping units for which product sales are greater than zero to be 55,600. Assuming that the flow of new products is 10 percent per year, then each year approximately 5,560 new dietary supplement products are projected to enter the market. Estimating that there are 1,700 dietary supplement manufacturers, re-packagers, re-labelers, and holders of dietary supplements subject to the information collection requirement (using the figure 1,460 as provided in our final rule of June 25, 2007 (72 FR 34752), on the “Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements,” and factoring for a 2 percent annual growth rate), we calculate an annual disclosure burden of 3.27 disclosures (labels) per firm. Last, we expect that firms prepare the required labeling for their products in a manner that takes into account at one time all information required to be disclosed and therefore believe that less than 0.2 hours (12 minutes) per product label would be expended to fulfill this requirement.

In row 2 of table 1 we estimate the total burden associated with the recommendation to include an explanatory statement on dietary supplement product labels letting consumers know the purpose of the domestic address or telephone number to be 1,112 hours. Based upon our knowledge of food and dietary supplement labeling, we estimate it would require less than 0.2 hours (12 minutes) per product label to include such a statement.

Dated: August 17, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-20760 Filed 8-21-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-0001]

#### Surrogate Endpoints for Clinical Trials in Kidney Transplantation; Notice of Public Workshop; Correction

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of Monday, August 3, 2015 (80 FR 45999). The document announced a public workshop entitled “Surrogate Endpoints for Clinical Trials in Kidney Transplantation.” The document was published without the email address and fax number in the *Contact Person* section and without the option for email or phone registration in the *Registration* section. This document corrects those errors.

**FOR FURTHER INFORMATION CONTACT:** Ramou Pratt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6193, Silver Spring, MD 20993-0002, 301-796-3928 or 301-796-1600, FAX: 301-595-7993, [endpoints@fda.hhs.gov](mailto:endpoints@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2015-18911, appearing on page 45999 in the **Federal Register** of Monday, August 3, 2015, the following corrections are made:

1. On page 45999, in the first column, the *Contact Person* section is corrected to read: “*Contact Person:* Ramou Pratt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6193, Silver Spring, MD 20993-0002, 301-796-3928 or 301-796-1600, FAX: 301-595-7993, [endpoints@fda.hhs.gov](mailto:endpoints@fda.hhs.gov).”

2. On page 45999, in the second column, the *Registration* section is corrected to read: “*Registration:* Email, fax, or phone your registration information (including name, title, firm name, address, telephone and fax numbers) to Ramou Pratt (see *Contact Person*) by September 25, 2015. Registration is free for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space-available basis beginning at 8 a.m.

If you need special accommodations because of a disability, please contact Ramou Pratt (see *Contact Person*) at least 7 days in advance.”

Dated: August 19, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-20832 Filed 8-21-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0302-60D]

### Agency Information Collection Request. 60-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

#### Agency Information Collection Request. 60-Day Public Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request 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 functions; (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. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, email your request, including your address, phone number, OMB number, and OS document identifier, to [Sherette.funncoleman@hhs.gov](mailto:Sherette.funncoleman@hhs.gov), or call the Reports Clearance Office on (202) 690-6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above email address within 60-days.

*Proposed Project:* Medical Reserve Corps Unit Profile and Reports (Revision)—OMB No. 0990-0302—Office of the Secretary/Office of the Assistant Secretary for Health/Office of the Surgeon General/Division of Civilian Volunteer Medical Reserve Corps (OS/OASH/OSG/DCVMRC) is changed to Office of the Secretary/Office of the Assistant Secretary for Preparedness and Response/Office of Emergency Management/Division of the Civilian Volunteer Medical Reserve Corps this reorganization was effective as of 26 November 2014 as published in the **Federal Register** [FR Doc. 2014-28030 Filed 11-25-14; 8:45am].

*Abstract:* Medical Reserve Corps units are currently located in almost 1,000 communities across the United States,

and represent a resource of more than 205,000 volunteers. In order to continue supporting the MRC units in communities across the United States, and to continue planning for future emergencies that are national in scope, detailed information about the MRC units, including unit demographics,

contact information (regular and emergency), volunteer numbers, and information about activities is needed by the Division of Civilian Volunteer Medical Reserve Corps (DCVMRC). MRC Unit Leaders are asked to update this information on the MRC Web site at least quarterly, and to participate in a

Technical Assistance Assessment at least annually. The MRC unit data collected has expanded to include a self-assessment tool for use by unit leaders to aid in developing their MRC unit. This OMB revision request is for 3 years.

ESTIMATED ANNUALIZED BURDEN TABLE

Collection tool	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Unit Profile .....	MRC Unit Leader .....	1,000	4	30/60	2,000
TA Assessment .....	MRC Unit Leader .....	1,000	1	1	1,000
Factors for Success .....	MRC Unit Leader .....	1,000	4	30/60	2,000
Unit Activity Reporting .....	MRC Unit Leader .....	1,000	4	15/60	1,000
<b>Total .....</b>					<b>6,000</b>

**Terry S. Clark,**

*Asst Information Collection Clearance Officer.*

[FR Doc. 2015-20848 Filed 8-21-15; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Notice To Propose the Redesignation of the Service Delivery Area for the Wampanoag Tribe of Gay Head (Aquinnah)**

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice advises the public that the Indian Health Service (IHS) proposes to expand the geographic boundaries of the Service Delivery Area for the Wampanoag Tribe of Gay Head (Aquinnah) of Massachusetts. The Aquinnah service delivery area is currently comprised of members of the Tribe residing in Martha's Vineyard, Dukes County in the State of Massachusetts.

The Bureau of Indian Affairs (BIA) recognized the Wampanoag Tribe of Gay Head on February 10, 1987. Martha's Vineyard, Dukes County was designated as the Aquinnah service delivery area in the Wampanoag Tribal Council of Gay Head, Inc., Indian Claims Settlement Act of 1987, Public Law 100-95.

**DATES:** Comments must be submitted September 23, 2015.

**ADDRESSES:** Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a Comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Betty Gould, Regulations Officer, Indian Health Service, 801 Thompson Avenue, TMP STE 450, Rockville, Maryland 20852.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the above address.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to the address above. If you intend to deliver your comments to the Rockville address, please call telephone number (301) 443-1116 in advance to schedule your arrival with a staff member.

Comments will be made available for public inspection at the Rockville address from 8:30 a.m. to 5:00 p.m., Monday-Friday, two weeks after publication of this notice.

**FOR FURTHER INFORMATION CONTACT:** Carl Harper, Director, Office of Resource Access and Partnerships, Indian Health Service, 801 Thompson Avenue, Suite 360, Rockville, Maryland 20852. Telephone 301/443-2694 (This is not a toll free number).

**SUPPLEMENTARY INFORMATION:** *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment.

*Background:* The IHS currently provides services under regulations

codified at 42 CFR part 136, subparts A through C. Subpart C defines a Contract Health Service Delivery Area (CHSDA), now known as a Purchased/Referred Care (PRC) Service Delivery Area, as the geographic area within which PRC will be made available by the IHS to members of an identified Indian community who reside in the area. Residence in a PRC service delivery area by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12, creates no legal entitlement to PRC but only potential eligibility for services. Services needed but not available at an IHS/Tribal facility are provided under the PRC program depending on the availability of funds, the person's relative medical priority, and the actual availability and accessibility of alternate resources in accordance with the regulations.

As applicable to the Tribes, these regulations provide that, unless otherwise designated, a PRC service delivery area shall consist of a county which includes all or part of a reservation and any county or counties which have a common boundary with the reservation. (42 CFR 136.22(a)(6) (2014)). The regulations also provide that after consultation with the Tribal governing body or bodies on those reservations included within the PRC service delivery area, the Secretary may from time to time, redesignate areas within the United States for inclusion in or exclusion from a PRC service delivery area. The regulations require that certain criteria must be considered before any redesignation is made. The criteria are as follows:

- (1) The number of Indians residing in the area proposed to be so included or excluded;
- (2) Whether the Tribal governing body has determined that Indians residing in