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**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Julia Tait Lathrop, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5614, Silver Spring, MD 20993, 240-402-5034, [julia.lathrop@fda.hhs.gov](mailto:julia.lathrop@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of March 9, 2016, (81 FR 12511), FDA published a notice of a public workshop with a deadline of April 20, 2016, to request comments on the workshop topics concerning the use of LC/MS-based IVDs in the clinical laboratory. Comments on the public workshop topics will inform FDA's development and validation of LC/MS-based devices, especially validation considerations for protein- and peptide-based LC/MS devices.

FDA is reopening the comment period for the notice of the public workshop until June 2, 2016. The Agency believes that the extension allows adequate time for interested persons to submit comments without significantly

delaying decision making on these important issues.

Dated: April 26, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-1160]

#### Center for Biologics Evaluation and Research eSubmitter Program for Electronic Submission of Postmarketing Adverse Event Reports for Human Vaccine Products

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency), Center for Biologics Evaluation and Research (CBER) is announcing the availability of a Vaccine Adverse Event Reporting System (VAERS) eSubmitter program for the electronic submission of postmarketing individual case safety reports (ICSRs) and ICSR attachments of adverse events for human vaccine products (VAERS eSubmitter program). The VAERS eSubmitter program is a free software program for voluntary use that is intended to help persons subject to mandatory postmarketing requirements for vaccines including applicants, manufacturers, packagers, and distributors to electronically submit ICSRs and ICSR attachments as required by the final rule titled "Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements." The VAERS eSubmitter program creates a simple and efficient mechanism for the secure electronic submission of postmarketing ICSRs and ICSR attachments into the VAERS database without the need for an internal database that is compatible with the International Conference on Harmonisation (ICH)-based direct database to database submission system.

**FOR FURTHER INFORMATION CONTACT:** Bioinformatics Support Staff, Office of Review Management, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, [CBERICSRSUBMISSIONS@fda.hhs.gov](mailto:CBERICSRSUBMISSIONS@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

### I. Background

FDA is announcing the availability of the VAERS eSubmitter program for the electronic submissions of postmarketing ICSRs and ICSR attachments of adverse events for human vaccine products. The VAERS eSubmitter program is available for voluntary use by applicants and others required to report postmarketing adverse events, as described above, to submit an initial or follow-up ICSR document for human vaccine products. The eSubmitter application software, which can be downloaded free of charge, assists users in the preparation of submissions that contain the minimum elements necessary for FDA to perform a comprehensive review.

The eSubmitter ICSR template for vaccines is designed to ensure that those submitting postmarketing ICSRs and ICSR attachments include necessary information in these regulatory submissions. It is also designed to guide users of the system as they complete the ICSR file creation and submission process. The VAERS eSubmitter program will help to improve the consistency, quality, and completeness of ICSR submissions and make the submission and review process more user-friendly for those required to report postmarketing adverse events for human vaccine products.

FDA published in the **Federal Register** of June 10, 2014 (79 FR 33072), a final rule titled "Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements," which requires, in part, that applicants and other adverse event reporters submit postmarketing ICSRs and ICSR attachments to CBER in an electronic format that the Agency can process, review, and archive. The final rule became effective June 10, 2015. Postmarketing ICSRs and ICSR attachments sent to CBER for human vaccines are processed into the VAERS database. As discussed in the preamble to the final rule and in CBER's final guidance for industry "Providing Submissions in Electronic Format—Postmarketing Safety Reports for Vaccines," dated August 2015 (August 2015 Guidance), FDA is providing two voluntary options for electronic submission of ICSRs and ICSR attachments into VAERS: (1) Direct database to database submission through the Electronic Submissions Gateway (ESG), and (2) submission of safety reports through the VAERS eSubmitter program as described on the CBER eSubmitter Web page (available at: <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm191387.htm>). Applicants and others required to report

postmarketing adverse events can choose either option to electronically submit ICSRs and ICSR attachments to VAERS.

The ICSR eSubmitter software is a government-issued software provided in support of the Government Paperwork Elimination Act of 1998 (44 U.S.C. 3504). As users of the eSubmitter software, applicants and others required to report postmarketing adverse events are not required to perform their own file validation process. The purpose of the ICSR eSubmitter template is to facilitate the electronic submission of postmarketing vaccine safety reports using internationally adopted data standards to enhance regulatory review, exchange and dissemination of vaccine safety information. Applicants and others who choose to use the eSubmitter program for required postmarketing reporting of adverse events for human vaccine products must first download the eSubmitter software and then manually enter information into the ICSR template form to create each electronic ICSR or ICSR attachment for submission to FDA through the ESG for uploading to the VAERS database. Further information on submitting ICSRs and ICSR attachments using eSubmitter is included in the August 2015 Guidance (available at: <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/default.htm>), and on the CBER eSubmitter Web page referenced above.

Dated: April 25, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-10025 Filed 4-28-16; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Health Resources and Services Administration**

#### **Statement of Organization, Functions and Delegations of Authority**

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 80 FR 19981-19982 dated April 6, 2016).

This notice reflects organizational changes in the Health Resources and

Services Administration (HRSA), Office of the Administrator (RA). Specifically, this notice: (1) Renames the Office of Equal Opportunity, Civil Rights and Diversity Management (RA2) to the Office of Civil Rights, Diversity and Inclusion (RA2); and (2) updates the functional statement for Office of Civil Rights, Diversity and Inclusion (RA2).

#### **Chapter RA2—Office of Civil Rights, Diversity and Inclusion**

##### *Section RA2-00, Mission*

The mission of the Office of Civil Rights, Diversity and Inclusion is to protect and serve the rights of all HRSA employees, applicants and beneficiaries of federal funds by enforcing federal laws, policies and practices prohibiting discrimination, resolves workplace disputes and conflict at the earliest possible stage, and helps to leverage diversity throughout HRSA.

##### *Section RAE-10, Organization*

Delete the organization for the Office of the Administrator (RA) in its entirety and replace with the following:

Rename the Office of Equal Opportunity, Civil Rights and Diversity Management to the Office of Civil Rights, Diversity and Inclusion within the Office of the Administrator. The Office of the Administrator is headed by the Administrator, who reports directly to the Secretary, Department of Health and Human Services.

- (1) Immediate Office of the Administrator (RA);
- (2) Office of Legislation (RAE);
- (3) Office of Communications (RA6);
- (4) Office of Health Equity (RAB);
- (5) Office of Civil Rights, Diversity and Inclusion (RA2);
- (6) Office of Planning, Analysis and Evaluation (RA5);
- (7) Office of Women's Health (RAW); and
- (8) Office of Global Health (RAI).

##### *Section RA2-20, Functions*

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA), Office of the Administrator (RA). Specifically, this notice: (1) Updates the functional statement.

Delete the function for the Office of Equal Opportunity, Civil Rights and Diversity Management and replace in its entirety.

#### **Office of Civil Rights, Diversity and Inclusion (RA2)**

Serves as the focal point for HRSA's formulation, implementation,

coordination and management of the equal opportunity, civil rights, and diversity and inclusion activities. Specifically: (1) Provides advice, counsel, and recommendations to HRSA personnel, including regional offices, on equal opportunity, civil rights, and diversity and inclusion issues; (2) analyzes Agency data to determine underrepresentation and/or underutilization of diverse groups in the workforce; (3) identifies barriers and devises strategies to eliminate those barriers; (4) manages the equal employment opportunity complaint process for HRSA civilian employees; (5) manages the equal employment opportunity complaint process for Public Health Service (PHS) Commissioned Corps personnel under the provisions of PHS Personnel Instruction 6 and issues recommendations to the Surgeon General; (6) approves and executes equal opportunity complaint settlement agreements; (7) develops and directs implementation of the requirements of Section 504 of the Rehabilitation Act of 1973, Title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975, the Americans With Disabilities Act, The Genetic Information Nondiscrimination Act of 2008, and Section 1557 of the Affordable Care Act, as they apply to HRSA and recipients of HRSA funds; (8) provides comprehensive EEO, Civil Rights and Diversity and Inclusion training to HRSA's supervisors, managers and employees to prevent discrimination and harassment in the workplace; (9) applies all applicable laws, guidelines, rules and regulations; and (10) provides leadership and guidance in HRSA's efforts to develop and maintain a diverse and inclusive workforce.

##### *Delegations of Authority*

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon date of signature.

Dated: April 21, 2016.

**James Macrae,**

*Acting Administrator.*

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