• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

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: Linda M. Wilmot, Center for Veterinary Medicine (HFV–120), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0829, *linda.wilmot@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 9, 2014 (79 FR 53431), FDA announced that it was beginning to explore possible modifications to the current review processes for NADAs for the use of multiple new animal drugs in combination drug medicated feeds. This effort is consistent with the stated performance goal in the Animal Drug User Fee Amendments of 2013 (ADUFA III) goals letter.

In the same notice, FDA announced the opening of a docket to receive public input. Originally, interested persons were given until September 9, 2015, to provide comment. In a February 13, 2015 (80 FR 8092), notice of a public meeting on this subject, FDA extended the comment period until March 31, 2016. At this time, FDA is reopening the comment period until July 29, 2016.

A summary of FDA recommendations, ''Recommendations on the Regulation of Combination Drug Medicated Feeds,'' has been placed in the FDA Docket. Persons with access to the Internet may obtain this document at the CVM FOIA Electronic Reading Room: *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm.*

Dated: April 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10028 Filed 4–28–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0610]

Mass Spectrometry in the Clinic: Regulatory Considerations Surrounding Validation of Liquid Chromatography-Mass Spectrometry Based Devices; Public Workshop; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of a public workshop that appeared in the **Federal Register** of March 9, 2016. In the notice of the public workshop, FDA requested comments on the workshop topics concerning the use of liquid chromatography/mass-spectrometry (LC/MS)-based in vitro diagnostic devices (IVDs) in the clinical laboratory. The Agency is taking this action in response to requests to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period for the notice of public workshop published March 9, 2016. Submit either electronic or written comments by June 2, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–0610 for ''Mass Spectrometry in the Clinic: Regulatory Considerations Surrounding Validation of Liquid Chromatography-Mass Spectrometry Based Devices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two

copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

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*.

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.

[FR Doc. 2016–10106 Filed 4–28–16; 8:45 am]

BILLING CODE 4164–01–P

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*.

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