concerning its policies on advance directives.

- § 416.50(c)(2), to ensure the patient or the patient's representative is informed of the right to make informed decisions regarding the patient's care.
- § 416.50(f)(3), to ensure the patient has the right to be free from all forms of abuse or harassment.
- § 416.51(b)(3), to provide a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.
- § 416.52(a)(1), to ensure each patient receives a comprehensive medical history and physical not more than 30 calendar days before the date of the scheduled surgery.
- § 416.52(c)(1), to address the ASCs responsibility to provide overnight supplies when discharged from the ASC.
- § 416.52(c)(2), to ensure each patient has a discharge order, signed by a physician who performed the surgery or procedure in accordance with applicable state health and safety laws, standards of practice, and ASC policy.
- § 416.52(c)(3), to ensure all patients are discharged in the company of a responsible adult unless exempted by the attending physician.
- § 488.5(a)(4)(ii), to ensure IMQ's surveyors observe at least one surgical procedure during an onsite ASC survey.
- § 488.5(a)(4)(iv), to ensure each statement of deficiency contains a clear, detailed description of the deficient practice and relevant findings that includes the use of numerators and denominators, when applicable, as well as a regulatory reference based on the relevant Medicare requirement.
- § 488.5(a)(9), to ensure IMQ's evaluation system used to monitor the performance of its surveyors meets the Medicare requirements.
- § 488.5(a)(12), to ensure IMQ's policies for responding to and investigating complaints against accredited facilities meets the Medicare requirements.
- § 489.13(b), to ensure IMQ does not provide an effective date of accreditation until the facility meets all applicable federal requirements, this includes both the Medicare requirements and IMQ standards.
- § 488.20(b) and § 488.28(a), to ensure that IMQ has a policy regarding our requirements for submission of a plan of correction by the ASC and the completion of an onsite follow-up survey to determine compliance with the Medicare CfCs after citing condition level noncompliance during a recertification survey.
- Section 2005A of the State Operations Manual (SOM), to ensure that IMQ has a policy regarding condition level noncompliance identified during an initial accreditation survey for participation in Medicare.
- Section 2700 of the SOM, to ensure all Medicare surveys are conducted on an unannounced basis.
- Section 2728 of the SOM, to ensure policies regarding timeframes for sending and receiving a plan of correction meets the Medicare requirements.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we approve IMQ as a national accreditation organization for ASCs that request participation in the Medicare program, effective April 29, 2016 through April 29, 2020.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Dated: April 13, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–10165 Filed 4–28–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1050]

Recommendations on the Regulation of Combination Drug Medicated Feeds; Availability; Reopening of Comment Period; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of comment period; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period and requesting public input on possible modifications to the current review processes for new animal drug applications (NADAs) for the use of multiple new animal drugs in combination drug medicated feeds. We are also announcing the availability of a Center for Veterinary Medicine (CVM) recommendations document for the animal drug user fee negotiating committee.

DATES: Submit either electronic or written comments by July 29, 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–2014–N–1050 for ''Regulation of Combination Drug Medicated Feeds.'' 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: 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