TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section and activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Supplemental Feed Mill License Application Using Form FDA 3448 (515.11(b)).	40	1	40	0.25 (15 minutes)	10
Voluntary Revocation of Medicated Feed Mill License (515.23).	40	1	40	0.25 (15 minutes)	10
Filing a Request for a Hearing on Medicated Feed Mill License (515.30(c)).	1	1	1	4	4
Total					29

[1] ''There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section and activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of Records for Approved Labeling for Each ''Type B'' and ''Type C'' Feed (510.305).	890	1	890	0.03 (2 minutes)	26.7

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on our experience with medicated feed mill license applications. We estimate that we will receive 20 medicated feed mill license applications, 40 supplemental applications, 40 requests for voluntary revocation, and that these submissions will take approximately 15 minutes per response, as shown in table 1, rows 1 through 3. We estimate that preparing a request for a hearing under 21 CFR 515.30(c) takes approximately 4 hours, as shown in table 1, row 4. In table 2, we estimate that 890 licensees will keep the records required by 21 CFR 510.305 expending a total of 26.7 hours annually.

Dated: March 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05214 Filed 3–8–16; 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; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Mass Spectrometry in the Clinic: Regulatory Considerations Surrounding Validation of Liquid Chromatography-Mass Spectrometry Based Devices.'' The topics to be discussed are the specific analytical and clinical study designs and considerations for validation and use of liquid chromatography/mass-spectrometry (LC/MS)-based in vitro diagnostic devices (IVDs) in the clinical laboratory. The primary focus will be on the validation considerations with protein- and peptide-based LC/MS devices.

DATES: The public workshop will be held on May 2, 2016, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on the public workshop by April 20, 2016.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (The Great Room), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

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 the ''Mass Spectrometry in the Clinic: Regulatory Considerations Surrounding Validation of Liquid Chromatography-Mass Spectrometry Based Devices'' public workshop. 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, email: *julia.lathrop@fda.hhs.gov.*

I. Background

Innovations in liquid chromatography-mass spectrometry (LC/MS) technology have dramatically improved assay throughput and precision.[1] FDA has cleared and approved several LC/MS- and MS-based devices as diagnostic tests, including assays for screening newborns for metabolic diseases, for identifying microbes from human cultures, and for measuring the concentrations of therapeutic drugs in blood. Currently, however, no LC/MS-based IVDs have been cleared or approved by FDA for measuring proteins and peptides. FDA would like to enhance engagement with the clinical LC/MS community concerning the development and validation of LC/MS-based devices and to work with the community toward developing guidelines for review that will be useful and relevant to both FDA and manufacturers. Prior to the workshop, FDA will place a discussion paper on file in the public docket (docket number found in brackets in the heading of this document) and will post it at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.*

II. Topics for Discussion

This public workshop will consist of brief presentations providing information to frame the goals of the workshop, followed by interactive panel discussions. The presentations will focus on current and anticipated uses for LC/MS and discussions of different validation approaches. Following the presentations, a moderated discussion will ask speakers and additional panelists to provide their individual perspectives. Examples of topics for discussion surrounding the challenges to validation that are specific to LC/MS-based protein and peptide IVDs include:

• Identifying pre-analytical and analytical variables that impact precision and reproducibility;

• Defining methods of normalization, harmonization, and the use of internal standards for quantitation and device calibration;

• Developing quality control materials; and

• Identifying appropriate reference materials and predicate devices.

We are soliciting comments and feedback from the clinical LC/MS community regarding additional topics for FDA to consider. We anticipate that the comments and suggestions generated through this workshop will help facilitate the development of appropriate analytical and clinical validation methods for IVDs. The agenda of the workshop will include time for public comments. These comments can be submitted to the docket prior to the meeting (see **ADDRESSES**).

Registration: Registration is free and early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. Persons interested in attending this public workshop must register online by 4 p.m. on April 22, 2016. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, 301–796–5661, *susan.monahan@fda.hhs.gov,* no later than April 15, 2016.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan (contact for special accommodations) to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. The Webcast link will be available on the registration Web page after April 25, 2016. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Requests for Oral Presentations: This public workshop includes a public comment session and topic-focused sessions. During online registration you may indicate if you wish to present during a public comment session or

[1] LC/MS includes high-performance liquid chromatography, HPLC–MS.

participate in a specific session, and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comments and participate in the focused sessions. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by April 24, 2016. All requests to make oral presentations must be received by the close of registration at 4 p.m. on April 22, 2016. If selected for presentation, any presentation materials must be emailed to Julia Tait Lathrop (see **FOR FURTHER INFORMATION CONTACT**) no later than April 29, 2016. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

FDA is holding this public workshop to obtain information on current and anticipated uses for LC/MS as well as different validation approaches. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. For the deadline for submitting comments related to this public workshop, see **DATES**.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.* A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

Dated: March 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05220 Filed 3–8–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Reimbursement Rates for Calendar Year 2016

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: Notice is given that the Principal Deputy Director of the Indian Health Service (IHS), under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248 and 249(b)), Public Law 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*), has approved the following rates for inpatient and outpatient medical care provided by IHS facilities for Calendar Year 2016 for Medicare and Medicaid beneficiaries, beneficiaries of other Federal programs, and for recoveries under the Federal Medical Care Recovery Act (42 U.S.C. 2651–2653). The Medicare Part A inpatient rates are excluded from the table below as they are paid based on the prospective payment system. Since the inpatient per diem rates set forth below do not include all physician services and practitioner services, additional payment shall be available to the extent that those services are provided.

INPATIENT HOSPITAL PER DIEM RATE (EXCLUDES PHYSICIAN/PRACTITIONER SERVICES)

[Calendar year 2016]

Lower 48 States	$2,655
Alaska	3,335
Outpatient per Visit Rate (Excluding Medicare):	
Lower 48 States	368
Alaska	603
Outpatient Per Visit Rate (Medicare):	
Lower 48 States	324
Alaska	582
Medicare Part B Inpatient Ancillary Per Diem Rate:	
Lower 48 States	637
Alaska	1,082
Outpatient Surgery Rate (Medicare):	
Established Medicare rates for freestanding Ambulatory Surgery Centers..	

Effective Date for Calendar Year 2016 Rates

Consistent with previous annual rate revisions, the Calendar Year 2016 rates will be effective for services provided on/or after January 1, 2016 to the extent consistent with payment authorities including the applicable Medicaid State plan.

Dated: March 3, 2016.

Mary Smith,

Principal Deputy Director, Indian Health Service.

[FR Doc. 2016–05252 Filed 3–8–16; 8:45 am]

BILLING CODE 4160–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Integrative Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Integrative Health Special Emphasis Panel; Mind and Body Interventions.

Date: April 8, 2016.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Martina Schmidt, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Complementary and Integrative Health, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, 301–594–3456, *schmidma@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: March 3, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–05197 Filed 3–8–16; 8:45 am]

BILLING CODE 4140–01–P