MD 20993–0002, (301) 796–6218, email: *raquel.peat@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 8, 2011, FDA published a notice announcing a public meeting for the ''Advancing Regulatory Science for Highly Multiplexed Microbiology/Medical Countermeasure Devices,'' and opening of a public docket to seek input and comments from interested stakeholders to discuss the concept paper [1] for FDA's proposed evaluation approach for assessing the performance of highly multiplexed microbiology/MCM devices, including the following topics:

1. *Clinical Application of Highly Multiplexed Microbiology Devices:* Their clinical application and public health/clinical needs; inclusion of MCM-related pathogens that are expected to be rarely present in the tested specimens; the composition of clinically relevant panels of pathogens; the interpretation of the test results taking into consideration the possible detection of microorganisms that are not clinically relevant, and what is known and unknown about co-infections.

2. *Device Evaluation:* How to evaluate the analytical and clinical performance of highly multiplexed microbiology devices; approaches to device validation when positive specimens are not easily available, which is the case for many MCM pathogens; the sufficiency, feasibility, and practicality of the proposed FDA evaluation approach to establish device performance.

3. *Reference Databases:* Quality criteria for establishing the accuracy of reference databases; methods for curating, maintaining, and updating these databases; what is the current practice for creating and maintaining reference databases.

In the **Federal Register** notice of August 8, 2011, interested persons were originally given until September 13, 2011, to submit comments.

II. Request for Comments

Following publication of the August 8, 2011, **Federal Register** notice and posting of the concept paper, FDA received requests to allow interested persons additional time to comment. The Agency has considered the requests and is reopening the comment period until December 21, 2011.

[1] This concept paper may be found at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm267410.htm.*

III. How To Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in Section I of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–29937 Filed 11–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 11, 2012, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is (301) 977–8900.

Contact Person: Avena Russell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring, MD 20993–0002, *Avena.Russell@fda.hhs.gov,* (301) 796–3805, or FDA Advisory Committee Information Line, 1–(800) 741–8138 (301) 443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On January 11, 2012, the committee will discuss, make recommendations, and vote on information related to the premarket approval application, sponsored by Torax Medical, Inc., for the LINX Reflux Management System, a sterile, single use, surgically placed device used to treat the symptoms associated with gastroesophageal reflux disease.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before December 30, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 22, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 23, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact James Clark, at *James.Clark@fda.hhs.gov* or (301) 796–5293, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–29890 Filed 11–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–0165.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995.

Proposed Project: Health Professions Student Loan (HPSL) Program and Nursing Student Loan (NSL) Program Administrative Requirements (Regulations and Policy) (OMB No. 0915–0047)—[Extension]

The regulations for the Health Professions Student Loan (HPSL) Program and Nursing Student Loan (NSL) Program contain a number of reporting and recordkeeping requirements for schools and loan applicants. The requirements are essential for assuring that borrowers are aware of rights and responsibilities, know the history and status of each loan account in order to pursue aggressive collection efforts to reduce default rates, and that they maintain adequate records for audit and assessment purposes. Schools are free to use improved information technology to manage the information required by the regulations.

The estimated total burden is 49,487 hours. The burden estimates are as follows:

RECORDKEEPING REQUIREMENTS

Regulatory/section requirements	Number of record-keepers	Hours per year	Total burden hours
HPSL Program:			
57.206(b)(2), Documentation of Cost of Attendance	435	1.17	509
57.208(a), Promissory Note	435	1.25	544
57.210(b)(1)(i), Documentation of Entrance Interview	435	1.25	544
57.210(b)(1)(ii), Documentation of Exit Interview	*477	0.33	157
57.215(a) & (d), Program Records	*477	10	4,770
57.215(b), Student Records	*477	10	4,770
57.215(c), Repayment Records	*477	18.75	8,944
HPSL Subtotal	.....	.....	20,238
NSL Program:			
57.306(b)(2)(ii), Documentation of Cost of Attendance	304	0.3	91
57.308(a), Promissory Note	304	0.5	152
57.310(b)(1)(i), Documentation of Entrance Interview	304	0.5	152
57.310(b)(1)(ii), Documentation of Exit Interview	*486	0.17	83
57.315(a)(1) & (a)(4), Program Records	*486	5	2,430
57.315(a)(2), Student Records	*486	1	486
57.215(b)(3), Repayment Records	*486	2.51	1,220
NSL Subtotal	.....	.....	4,614

*Includes active and closing schools.

HPSL data include active and closing Loans for Disadvantaged Students (LDS) program schools.

REPORTING REQUIREMENTS

Regulatory/Section requirements	Number of respondents	Responses per respondent	Total annual responses	Hours per response	Total burden hours
HPSL:					
57.206(a)(2), Student Financial Aid Transcript	4,600	1	4,600	0.25	1,150
57.208(c), Loan Information Disclosure	435	68.73	29,898	0.0833	2,490
57.210(b)(1)(i), Entrance Interview	435	68.73	29,898	0.167	4,993
57.210(b)(1)(ii), Exit Interview	*477	12	5,724	0.5	2,862
57.210(b)(1)(iii), Notification of Repayment	*477	30.83	14,706	0.167	2,456