TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
New SOPs [2]	218	1	218	48	10,464
SOP Update [2]	2,706	1	2,706	24	64,944
1271.47(d)	1,353	1	1,353	1	1,353
1271.50(a)	2,706	33.91	91,756	5	458,780
1271.55(d)(1)	2,706	33.91	91,756	1	91,756
1271.55(d)(2)	2,706	1	2,706	1	2,706
1271.55(d)(4)	2,706	1	2,706	120	324,720
1271.60(d)(3) and (d)(4) 1271.65(b)(3)(iii)	812	1	812	2	1,624
1271.155(f)	26	1.54	40	.25 (15 minutes)	10
1271.160(b)(3) and (b)(6)	1,694	12	20,328	1	20,328
1271.160(d)	1,694	12	20,328	1	20,328
1271.190(d)(2)	1,694	12	20,328	1	20,328
1271.195(d)	1,694	12	20,328	1	20,328
1271.200(e)	1,694	12	20,328	1	20,328
1271.210(d)	1,694	12	20,328	1	20,328
1271.230(a)	1,694	12	20,328	1	20,328
1271.230(c)	1,694	1	1,694	1	1,694
1271.260(d)	1,694	12	20,328	.25 (15 minutes)	5,082
1271.260(e)	1,694	365	618,310	.083 (5 minutes)	51,320
1271.265(c)(1)	1,694	1,196.49	2,026,861	.083 (5 minutes)	168,229
1271.265(c)(3)	847	1	847	1	847
1271.265(e)	1,694	1,196.49	2,026,861	.083 (5 minutes)	168,229
1271.270(a)	1,694	1,196.49	2,026,861	.25 (15 minutes)	506,715
1271.270(e)	2,165	2	4,330	.5 (30 minutes)	2,165
1271.290(d) and (e)	1,694	50.86	86,156	.25 (15 minutes)	21,539
1271.320(b)	1,353	5	6,765	1	6,765
Total					2,031,238

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Sections 1271.47(a), 1271.85(b)(2), 1271.160(b)(2) and (d)(1), 1271.180(a), 1271.190(d)(1), 1271.200(b), 1271.200(c), 1271.230(a), 1271.250(a), and 1271.265(e).

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
1271.55(a)	1,965	1,103	2,167,396	.5 (30 minutes)	1,083,698
1271.60(c) and (d)(2)	1,375	208	286,000	.5 (30 minutes)	143,000
1271.290(c)	1,694	1,196.49	2,026,861	.083 (5 minutes)	168,229
1271.290(f)	1,694	1	1,694	1	1,694
1271.370(b) and (c)	1,694	1,196.49	2,026,861	.25 (15 minutes)	506,715
Total					1,903,336

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

Dated: July 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–16692 Filed 7–11–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0816]

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

AGENCY: Office of the Commissioner, 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-Urology Panel and Radiological 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 September 9, 2013, from 8 a.m. to 6 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Information regarding special accommodations due to a disability,

visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Daniel Sigelman, Food and Drug Administration, Office of the Commissioner, 10903 New Hampshire Ave., Bldg. 32, Rm. 4254, Silver Spring, MD 20993–0002, 301–796–4706, *Daniel.Sigelman@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On September 9, 2013, the joint committee, convened by the Office of the Commissioner, will discuss current evidence on the risks and benefits of computed tomography colonography for screening of asymptomatic patients for colorectal cancer. The joint committee will provide advice that will assist FDA's consideration of evolving research on this topic and inform the Agency's continuing regulation of these devices.

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 meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues being discussed at the meeting pending before the committee. Written submissions may be made to the docket on or after July 12, 2013. 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 August 22, 2013. 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 August 29, 2013.

FDA has opened a docket for public comment on this meeting. The docket number is FDA–2013–N–0816. The docket will open for public comment on July 12, 2013. Comments received to the docket on or before September 3, 2013, will be provided to the committee before the meeting. Comments received after that date will not be provided to the committee, but will be taken into consideration by the Agency. The docket will remain open for 30 days after the meeting for additional written submissions.

Interested persons may submit either electronic comments regarding this meeting to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments received will be posted without change, including any personal information provided. It is only necessary to send one set of comments. Identify comments with the docket number FDA–2013–N–0816. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

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 Daniel Sigelman 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: July 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–16711 Filed 7–11–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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 Institute on Alcohol Abuse and Alcoholism Initial Review Group, Neuroscience Review Subcommittee.

Date: November 5, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIAAA, 5635 Fishers Lane, T508, Rockville, MD 20852.

Contact Person: Beata Buzas, Ph.D., Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, RM 2081, Rockville, MD 20852, 301–443–0800, *bbuzas@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.273, Alcohol Research Programs; National Institutes of Health, HHS)

Dated: July 8, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–16699 Filed 7–11–13; 8:45 am]

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