TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN (MEDICAL GASES) [1]

21 CFR section/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours) [1]	Total hours
SOP Maintenance	2,284	0.65	1,485	25	37,125
New startup SOPs	100	25	2,500	20	50,000
211.34—Consultants	2,284	0.25	571	0.5	286
211.67(c)—Equipment cleaning and maintenance	2,284	32.5	74,230	0.25	18,558
211.68—Changes in master production and control records or other records	2,284	2	4,568	1	4,568
211.68(a)—Automatic, mechanical, and electronic equipment	2,284	10	22,840	0.5	11,420
211.68(b)—Computer or related systems	2,284	5	11,420	0.25	2,855
211.72—Filters	2,284	0.25	571	1	571
211.80(d)—Components and drug product containers or closures	2,284	0.25	571	0.1	57
211.100(b)—Production and process controls	2,284	3	6,382	2	13,704
211.105(b)—Equipment identification	2,284	0.25	571	0.25	143
211.122(c)—Labeling and packaging material	2,284	50	114,200	0.25	28,550
211.130(e)—Labeling and packaging facilities	2,284	50	114,200	0.25	28,550
211.132(c)—Tamper-evident packaging	2,284	20	45,680	0.5	22,840
211.132(d)—Tamper-evident packaging	2,284	0.2	457	0.5	229
211.137—Expiration dating	2,284	3.25	7,423	0.33	2,450
211.160(a)—Laboratory controls	2,284	2	4,568	1	4,568
211.165(e)—Test methodology	2,284	1	2,284	1	2,284
211.166—Stability testing	2,284	1.3	2,969	0.33	980
211.173—Laboratory animals	2,284	1	2,284	0.25	571
211.180(e)—Production, control, and distribution records	2,284	0.2	457	0.25	114
211.180(f)—Procedures for notification of regulatory actions	2,284	0.2	457	1	457
211.182—Equipment cleaning and use log	2,284	1.3	2,969	0.16	475
211.184—Component, drug product container, closure, and labeling records	2,284	1.95	4,454	0.33	1,470
211.186—Master production and control records	2,284	10	22,840	2	45,680
211.188—Batch production and control records	2,284	16.25	37,115	1.3	48,250
211.192—Discrepancies in drug product production and control records	2,284	2	4,568	1	4,568
211.194—Laboratory records	2,284	25	57,100	0.5	28,550
211.196—Distribution records	2,284	25	57,100	0.25	14,275
211.198—Complaint files	2,284	5	11,420	1	11,420
211.204—Returned drug products	2,284	10	22,840	0.5	11,420
Total					396,988

[1] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format ''[number of minutes per response]/60''.

Dated: December 8, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26932 Filed 12–13–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4562]

Public Workshop on Safety Assessment for Investigational New Drug Safety Reporting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Safety Assessment for Investigational New Drug Safety Reporting; Public Workshop'' that appeared in the **Federal Register** of November 27, 2017. The document announced a public workshop to engage external stakeholders in discussions related to finalizing the draft guidance entitled ''Safety Assessment for IND Safety Reporting.'' The date of the meeting has changed.

FOR FURTHER INFORMATION CONTACT: Lauren Wedlake, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6362, Silver Spring, MD 20993, 301–796–2728, *Lauren.Wedlake@fda.hhs.gov.*

In the **Federal Register** of Monday, November 27, 2017, in FR Doc. 2017–25454, the following correction is made:

1. On page 56036, in the first column, in the first sentence of the **DATES** section, ''The public workshop will be held on January 11, 2018, from 9 a.m. to 4 p.m., Eastern Time.'' is corrected to read ''The public workshop will be held on March 8, 2018, from 9 a.m. to 4 p.m., Eastern Time.''

Dated: December 8, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26938 Filed 12–13–17; 8:45 am]

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