

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS ¹—Continued

21 CFR Section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
312.38(b) and (c)	117	1.3	152	28	4,256
312.42(e)	74	1.5	111	284	31,524
312.44(c) and (d)	17	1.1	19	16	304
312.45(a) and (b)	60	1.8	108	12	1,296
312.47(b)	43	1.5	65	160	10,400
312.53(c)	348	6.6	2,297	80	183,760
312.54(a) and (b)	1	1	1	48	48
312.55(b)	138	2.5	345	48	16,560
312.56(b) and (d)	14	1.6	22	80	1,760
312.58(a)	8	1	8	8	64
312.64(a) through (d)	6,003	3.5	21,010	24	504,240
312.70(a)	6	1	6	40	240
312.110(b)	21	1	21	75	1,575
312.130(d)	1	1	1	8	8
Total					4,350,287

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

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS ¹

21 CFR Section	Number of record-keepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
312.52(a)	139	1.4	195	2	390
312.57(a) and (b)	433	2.6	1,126	100	112,600
312.62(a)	5,570	1	5,570	40	222,800
312.62(b)	5,570	10	55,700	40	2,228,000
312.160(a)(3)	146	1.4	204	0.5	102
312.160(c)	146	1.4	204	0.5	102
Total					2,563,994

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

Dated: January 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0084]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Pretesting of Tobacco Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Pretesting of Tobacco Communications" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794, e-mail: Jonnalynn.Capezzuto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of August 6, 2010 (75 FR 47600), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0674. The approval expires on January 31, 2013. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: January 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0250]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Premarket Approval of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Premarket Approval of Medical Devices" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, Daniel.Gittleson@FDA.HHS.GOV.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 24, 2010