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.

[FR Doc. 2011–1758 Filed 1–26–11; 8:45 am]

BILLING CODE 4160–01–P

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 entitle "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.

[FR Doc. 2011–1757 Filed 1–26–11; 8:45 am]

BILLING CODE 4160–01–P

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

(75 FR 58396), 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 0910–0231. The approval expires on December 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.

[FR Doc. 2011–1756 Filed 1–26–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0357]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 23, 2010 (75 FR 57962), 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 0910–0466. The approval expires on January 31, 2014. 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.

[FR Doc. 2011–1755 Filed 1–26–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0143; (formerly Docket No. FDA–2008–D–0128)]

Drug-Induced Liver Injury: Are We Ready to Look?; Public Conference; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public conference entitled "Drug-Induced Liver Injury: Are We Ready to Look?" The public conference will be cosponsored with the American Association for the Study of Liver Diseases (AASLD) and the Pharmaceutical and Research Manufacturers of America to discuss and debate issues regarding drug-induced liver injury (DILI). The purpose of this conference is to consider the effect of the recommendations in the guidance for industry entitled "Drug-Induced Liver Injury: Premarketing Clinical Evaluation" since its publication in July 2009 and to seek suggestions for future revision.

DATES: The public conference will be held on March 23, 2011, from 8 a.m. to 6 p.m. and March 24, 2011, from 8 a.m. until 3:30 p.m. Submit either electronic or written comments on Agency guidance at any time.

ADDRESSES: The conference will take place at the National Labor College, 10000 New Hampshire Ave., Silver Spring, MD 20993.

Submit written requests for single copies of the 2009 guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the 2009 guidance document.

Submit electronic comments on the 2009 guidance and the issues and questions presented at the conference to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lana L. Pauls, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4307, Silver Spring, MD 20993–0002, 301–796–0518, e-mail: *lana.pauls@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In July 2009, FDA made available a guidance for industry entitled "Drug-Induced Liver Injury: Premarketing Clinical Evaluation" (*see* 74 FR 38035, July 30, 2009). The 2009 guidance explains that DILI has been the most frequent cause of safety-related drug marketing withdrawals for the past 50 years, and that hepatoxicity has limited the use of many drugs that have been approved and prevented the approval of others. It discusses methods of detecting DILI by periodic tests of serum enzyme activities and bilirubin concentration elevations, and how those laboratory tests might change over time, along with symptoms and physical findings, to allow estimation of severity of the injury. It suggests some rules for stopping or interrupting drug treatment, and the need to obtain additional clinical information to estimate the likelihood of the true cause. Public comments on the draft guidance were sought in 2007 and 2008, and those comments were taken into consideration when issuing the final guidance in July 2009.

II. The Public Conference

A. Why are we holding this conference?

The purpose of the 2011 conference is to discuss the most current information and thinking about how drugs cause liver injury and why certain individuals are more susceptible than others, combining views of both basic science and clinical experts, and selecting for specific debate and discussion issues such as:

- Liver injury and dysfunction in patients,
- Liver reaction to injury,
- Biomarkers and predictors of liver injury and dysfunction, and
- Postmarketing DILI.