TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Second postcard	60	1	60	.03 (2 min.)	2
Survey	35	1	35	.33 (20 min.)	12
Main Study					
Survey invitation letter	5,042	1	5,042	.08 (5 min.)	403
Reminder postcard	5,042	1	5,042	.03 (2 min.)	151
Non-response letter	4,173	1	4,173	.08 (5 min.)	334
Non-response questionnaire letter	4,073	1	4,073	.08 (5 min.)	326
Second postcard	3,063	1	3,063	.03 (2 min.)	92
Survey	1,765	1	1,765	.33 (20 min.)	582
Total					1927

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

II. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Aikin, K.J., J.L. Swasy, and A.C. Braman, ''Patient and Physician Attitudes and Behaviors Associated With DTC Promotion of Prescription Drugs—Summary of FDA Survey Research Results,'' 2004. (*http://www.fda.gov/downloads/Drugs/ScienceResearch/ResearchAreas/DrugMarketingAdvertisingandCommunicationsResearch/ucm152860.pdf*).

2. PhRMA Guiding Principles: Direct-to-Consumer Advertisements About Prescription Medicines 2008. (*http://phrma.org/sites/default/files/pdf/phrmaguidingprinciplesdec08final.pdf*).

3. Dillman, D.A., J.D. Smyth, and L.M. Christian, *Internet, Phone, Mail, and Mixed-Mode Surveys: The Tailored Design Method,* 4th ed. Hoboken, NJ: John Wiley & Sons, Inc., 2014.

4. American Association for Public Opinion Research, ''Address-based Sampling,'' 2016. (*http://www.aapor.org/AAPOR_Main/media/MainSiteFiles/AAPOR_Report_1_7_16_CLEAN-COPY-FINAL.pdf*).

5. Millar, M.M. and D.A. Dillman, ''Improving Response to Web and Mixed-Mode Surveys,'' *Public Opinion Quarterly* 1–21. 2011.

6. Shaw, M.J., T.J. Beebe, H.L. Jensen, and S.A. Adlis, ''The Use of Monetary Incentives in a Community Survey: Impact on Response Rates, Data Quality, and Cost,'' *Health Services Research* 35:1339–1346. 2011.

7. Montaquila, J.M., J.M. Brick, D. Williams, K. Kim, et al., ''A Study of Two-Phase Mail Survey Data Collection Methods,'' *Journal of Survey Statistics and Methodology* 1(1), 66–87. 2013.

Dated: July 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18425 Filed 8–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2012–N–1210; FDA–2004–N–0258]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Food Labeling: Nutrition Facts and Supplement Facts Label and Reference Amounts Customarily Consumed per Eating Occasion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Food Labeling: Nutrition Facts and Supplement Facts Label and Reference Amounts Customarily Consumed Per Eating Occasion'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On May 27, 2016, the Agency submitted a proposed collection of information entitled ''Food Labeling: Nutrition Facts and Supplement Facts Label and Reference Amounts Customarily Consumed Per Eating Occasion'' 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 0910–0813. The approval expires on July 31, 2019. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: August 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18509 Filed 8–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2016–M–1122, FDA–2016–M–1123, FDA–2016–M–1124, FDA–2016–M–1125, FDA–2016–M–1165, FDA–2016–M–1166, FDA–2016–M–1167, FDA–2016–M–1168, FDA–2016–M–1222, FDA–2016–M–1223, FDA–2016–M–1400, FDA–2016–M–1401, FDA–2016–M–1455, FDA–2016–M–1459, FDA–2016–M–1754, and FDA–2016–M–1755]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications

(PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2016–M–1122, FDA–2016–M–1123, FDA–2016–M–1124, FDA–2016–M–1125, FDA–2016–M–1165, FDA–2016–M–1166, FDA–2016–M–1167, FDA–2016–M–1168, FDA–2016–M–1222, FDA–2016–M–1223, FDA–2016–M–1400, FDA–2016–M–1401, FDA–2016–M–1455, FDA–2016–M–1459, FDA–2016–M–1754, and FDA–2016–M–1755 for ''Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–6524.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from April 1, 2016, through June 30, 2016. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM APRIL 1, 2016, THROUGH JUNE 30, 2016

PMA No., Docket No.	Applicant	Trade name	Approval date
P100044/S018, FDA–2016–M–1123	Intersect ENT	PROPEL® Mini Sinus Implant	3/23/2016
P150028, FDA–2016–M–1122	NuMed, Inc	Cheatham Platinum Stent System	3/25/2016
P150026, FDA–2016–M–1124	Cardiofocus, Inc	HeartLight Endoscopic Ablation System	4/1/2016

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM APRIL 1, 2016, THROUGH JUNE 30, 2016—Continued

PMA No., Docket No.	Applicant	Trade name	Approval date
P150033, FDA–2016–M–1125	Medtronic, Inc	Medtronic Micra™ Transcatheter Pacemaker System.	4/6/2016
P140003/S005, FDA–2016–M–1165	Abiomed, Inc	Impella Left Ventricular Support System	4/7/2016
P150041, FDA–2016–M–1167	Abbott Molecular, Inc	Vysis CLL FISH Probe Kit	4/11/2016
P150016, FDA–2016–M–1166	Neomend, Inc	TRIDYNE™ Vascular Sealant	4/11/2016
P130001, FDA–2016–M–1168	Epigenomics AG	Epi proColon	4/12/2016
P150012, FDA–2016–M–1222	Boston Scientific Corporation	ImageReady MR Conditional Pacing System and Ingevity Pace/Sense Lead.	4/25/2016
P130029/S002, FDA–2016–M–1223	Bard Peripheral Vascular, Inc	Fluency® Plus Endovascular Stent Graft	4/26/2016
P160002, FDA–2016–M–1400	Ventana Medical Systems, Inc	VENTANA PD–L1(SP142) Assay	5/18/2016
P070014/S037, FDA–2016–M–1455	Bard Peripheral Vascular, Inc	Bard® LifeStent Vascular Stent System	5/31/2016
P110033/S018, FDA–2016–M–1401	Allergan	JUVÉDERM VOLBELLA® XC	5/31/2016
P150047, FDA–2016–M–1459	Roche Molecular Systems, Inc	cobas® EGFR Mutation Test v2	6/1/2016
P150024, FDA–2016–M–1754	Aspire Bariatrics, Inc	AspireAssist®	6/14/2016
P150029, FDA–2016–M–1755	Medtronic Minimed, Inc	iPro2 Continuous Glucose Monitoring System With Enlite Sensor.	6/17/2016

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.*

Dated: August 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18508 Filed 8–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2066]

Agency Information Collection Activities; Proposed Collection; Comment Request; Certification of Identity for Freedom of Information Act and Privacy Act Requests

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on ''Certification of Identity for Freedom of Information Act and Privacy Act Requests.''

DATES: Submit either electronic or written comments on the collection of information by October 3, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–2066 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Certification of Identity for Freedom of Information Act and Privacy Act Requests.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover