TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
320.31(d) Bioavailability and Bioequivalence Safety Reports	10	20	200	14	2,800
312.32(c)(1)(ii) and (c)(1)(iii) IND Safety Reports	100	6	600	12	7,200
312.32(c)(1)(iv) IND Safety Reports	10	1	10	12	120
Total					10,120

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

Dated: June 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13904 Filed 6–11–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–M–0036, FDA–2013–M–0205, FDA–2013–M–0255, FDA–2013–M–0281, FDA–2013–M–0282, and FDA–2013–M–0343]

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: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993–0002, 301–796–6570.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 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 January 1, 2013, through March 31, 2013. 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 JANUARY 1, 2013, THROUGH MARCH 31, 2013

PMA No., docket No.	Applicant	Trade name	Approval date
P110014, FDA–2013–M–0036	Dune Medical Devices, Inc	MarginProbe System	December 27, 2012.
H110002, FDA–2013–M–0205	Second Sight Medical Products, Inc	Argus™ II Retinal Prosthesis System	February 13, 2013.
P110032, FDA–2013–M–0282	Lombard Medical	Aorfix AAA Flexible Stent Graft System	February 14, 2013.
P040046, FDA–2013–M–0255	Allergan	Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants.	February 20, 2013.
P110013/S005, FDA–2013–M–0343	Medtronic Vascular, Inc	Resolute Integrity Zotarolimus-Eluting Coronary Stent System.	February 22, 2013.
P100030, FDA–2013–M–0281	Tenaxis Medical, Inc	ArterX Surgical Sealant	March 1, 2013.

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: June 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13905 Filed 6–11–13; 8:45 am]

BILLING CODE 4160–01–P