

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 Pace-maker 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]

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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

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20851, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal

Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Certification of Identity for Freedom of Information Act and Privacy Act Requests OMB Control Number 0910—NEW

In compliance with 44 U.S.C. 3507, FDA will submit to the Office of Management and Budget a request to review and approve a new collection of information: Certification of Identity for Freedom of Information Act and Privacy Act Requests. This new form provides the FDA with data necessary to identify an individual requesting a particular record under the Freedom of Information Act (FOIA) and the Privacy

Act. The form is available at the following FDA FOIA page at: <http://www.fda.gov/RegulatoryInformation/FOI/default.htm>, although if an individual requests one, we will send it by mail or email. The FOIA grants the public a right to access Federal records not normally prepared for public distribution. The Privacy Act grants a right of access to members of the public who seek access to one’s own records that are maintained in an Agency’s system of records (*i.e.* the records are retrieved by that individual’s name or other personal identifier). The statutes overlap, and individuals who request their own records are processed under both statutes. The Agency may need to confirm that the individual making the FOIA or Privacy Act request is indeed the same person named in the Agency records.

Members of the public who wish to access particular records will be asked for certain information: Name, citizenship status, social security number, address, date of birth, place of birth, signature, and date of signature.

FDA estimates the burden of this collection of information as follows:

As stated in table 1, the estimates are based on the following: The number of FOIA and Privacy Act requests received by FDA each year that require a certification of identity in order for FDA to process the request. Of the 10,000 requests received per year, only a small number require a certification of identity. In some cases, the requesters provide their own certification of identity. Therefore, we have estimated the number of affected individuals at 60 per year.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3975	60	1	60	.17 (10 minutes)	10

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

Dated: July 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18463 Filed 8–3–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Requirements and Registration for the “MRC Serves” Video Challenge

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Medical Reserve Corps (MRC) Program housed under the Office of the Assistant Secretary for

Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS), announces the launch of the “MRC Serves” Video Challenge. The MRC is a national network of volunteers, organized locally to improve the health and safety of their communities. MRC volunteers have medical, public health, other backgrounds and have responded to natural disasters, public health and other emergencies, while also supporting community health activities. The MRC Program is looking for