Estimated Total Annual Burden Hours: 155,529.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget Paperwork Reduction Project Email: *OIRA_SUBMISSION@OMB.EOP.GOV. Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2018–25053 Filed 11–15–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–M–6970, FDA–2017–M–6971, FDA–2017–M–6983, FDA–2017–M–6984, FDA–2017–M–7004, FDA–2018–M–0411, FDA–2018–M–0528, FDA–2018–M–0620, FDA–2018–M–0736, FDA–2018–M–0737, FDA–2018–M–00–0738, FDA–2018–M–0792, FDA–2018–M–1371, FDA–2018–M–1215, FDA–2018–M–1237, FDA–2018–M–1372, FDA–2018–M–1446, FDA–2018–M–1447, FDA–2018–M–1580, FDA–2018–M–1581, FDA–2018–M–1634, FDA–2018–M–1727, FDA–2018–M–1791, FDA–2018–M–1753, FDA–2018–M–1970, FDA–2018–M–2118, FDA–2018–M–2119, FDA–2018–M–2237, FDA–2018–M–2269, FDA–2018–M–2335, FDA–2018–M–2460, FDA–2018–M–2461, FDA–2018–M–2462, FDA–2018–M–2463, FDA–2018–M–2571, FDA–2018–M–2883, FDA–2018–M–2884, FDA–2018–M–2885, FDA–2018–M–2886, FDA–2018–M–2887, FDA–2018–M–2983, FDA–2018–M–3131, FDA–2018–M–3153, FDA–2018–M–3212, FDA–2018–M–3503, FDA–2018–M–3505, and FDA–2018–M–3548]

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) and humanitarian device exemption applications (HDEs), 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 Dockets Management Staff.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2017–M–6970, FDA–2017–M–6971, FDA–2017–M–6983, FDA–2017–M–6984, FDA–2017–M–7004, FDA–2018–M–0411, FDA–2018–M–0528, FDA–2018–M–0620, FDA–2018–M–0736, FDA–2018–M–0737, FDA–2018–M–00–0738, FDA–2018–M–0792, FDA–2018–M–1371, FDA–2018–M–1215, FDA–2018–M–1237, FDA–2018–M–1372, FDA–2018–M–1446, FDA–2018–M–1447, FDA–2018–M–1580, FDA–2018–M–1581, FDA–2018–M–1634, FDA–2018–M–1727, FDA–2018–M–1791, FDA–2018–M–1753, FDA–2018–M–1970, FDA–2018–M–2118, FDA–2018–M–2119, FDA–2018–M–2237, FDA–2018–M–2269, FDA–2018–M–2335, FDA–2018–M–2460, FDA–2018–M–2461, FDA–2018–M–2462, FDA–2018–M–2463, FDA–2018–M–2571, FDA–2018–M–2883, FDA–2018–M–2884, FDA–2018–M–2885, FDA–2018–M–2886, FDA–2018–M–2887, FDA–2018–M–2983, FDA–2018–M–3131, FDA–2018–M–3153, FDA–2018–M–3212, FDA–2018–M–3503, FDA–2018–M–3505, and FDA–2018–M–3548 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 *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf* .

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 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 (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 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, 2018, through September 18, 2018. 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 AND SAFETY AND PROBABLE BENEFIT SUMMARIES FOR APPROVED HDES MADE AVAILABLE FROM JANUARY 1, 2018, THROUGH SEPTEMBER 18, 2018

PMA No., Docket No.	Applicant	Trade name	Approval date
P150005/S014, FDA–2017–M–6970.	Boston Scientific	Blazer® Open-Irrigated Ablation Catheter and IntellaNav™ Open-Irrigated Ablation Catheter.	12/21/2017
P100030/S008, FDA–2017–M–6971.	Mallinckrodt Pharma IP Trading DAC	PREVELEAK Surgical Sealant	12/21/2017
P160012, FDA–2017–M–6983	Physio-Control, Inc	LIFEPAK CR® Plus Defibrillator, LIFEPAK EXPRESS® Defibrillator and CHARGE–PAK® Battery Charger.	12/21/2017
P140032, FDA–2017–M–6984	Medtronic, Inc	Implantable System for Remodulin®	12/22/2017
P160022, FDA–2017–M–7004	ZOLL Medical Corp	X Series®, R Series®, AED Pro®, and AED 3™ BLS® Professional Defibrillators, Pro-Padz Radiotransparent Electrode, SurePower™ Battery Pack, SurePower II™ Battery Pack, AED Pro® Non-Rechargeable Lithium Battery Pack, AED 3™ Battery Pack, SurePower™ Charger, and SurePower™ Single Bay Charger.	12/27/2017
P170025, FDA–2018–M–0411	Hologic, Inc	Aptima® HBV Quant Assay	1/23/2018
P160032, FDA–2018–M–0528	Defibtech, LLC	Lifeline/ReviveR DDU–100, Lifeline/ReviveR AUTO DDU–120, Lifeline/ReviveR VIEW DDU–2300, Lifeline/ReviveR VIEW AUTO DDU–2200, Lifeline/ReviveR ECG DDU–2450, and Lifeline/ReviveR ECG+ DDU–2475 Automated External Defibrillators.	2/1/2018
P140003/S018, FDA–2018–M–0620.	Abiomed, Inc	Impella Ventricular Support Systems	2/7/2018
P160037, FDA–2018–M–0736	Becton, Dickinson and Co	BD Onclarity HPV Assay	2/12/2018
P150001/S021, FDA–2018–M–0737.	Medtronic MiniMed, Inc	MiniMed 630G System	2/13/2018
P160017/S017, FDA–2018–M–0738.	Medtronic MiniMed, Inc	MiniMed 670G System	2/13/2018
P960043/S097, FDA–2018–M–0792.	Abbott Vascular	Perclose ProGlide® Suture-Mediated Closure System	2/16/2018
P160007, FDA–2018–M–1371	Medtronic MiniMed, Inc	Guardian Connect System	3/8/2018
H170002, FDA–2018–M–1215	Kaneka Pharma America LLC	LIPOSORBER® LA–15 System	3/20/2018
P160013, FDA–2018–M–1237	TransMedics, Inc	Organ Care System (OCS™) Lung System	3/22/2018
P050006/S060, FDA–2018–M–1372.	W.L. Gore & Associates, Inc	GORE® CARDIOFORM Septal Occluder	3/30/2018
P160018/S001, FDA–2018–M–1446.	Foundation Medicine, Inc	FoundationFocus™ CDx *BRCA* LOH	4/6/2018
P150009, FDA–2018–M–1447	Angel Medical Systems, Inc	AngelMed Guardian System	4/9/2018
P160052, FDA–2018–M–1581	Parsagen Diagnostics, Inc	PartoSure Test	4/11/2018
P950039/S036, FDA–2018–M–1580.	Hologic, Inc	ThinPrep Integrated Imager	4/18/2018
P140010/S037, FDA–2018–M–1634.	Medtronic Vascular, Inc	IN.PACT™ Admiral™ Paclitaxel-Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter.	4/19/2018
P960009/S219, FDA–2018–M–1727.	Medtronic, Inc	Medtronic DBS System for Epilepsy	4/27/2018
P170035, FDA–2018–M–1791	Bausch + Lomb, Inc	Bausch + Lomb ULTRA (samfilcon A) Contact Lenses	4/30/2018
P170016, FDA–2018–M–1753	Teva Pharmaceuticals USA, Inc	SYNOJOYNT™	5/8/2018
P040024/S099, FDA–2018–M–1970.	Galderma Laboratories, LP	*Restylane® Lyft with Lidocaine*	5/18/2018
P170013, FDA–2018–M–2118	MicroVention, Inc	Low-Profile Visualized Intraluminal Support (LVIS) and LVIS Jr	5/30/2018
P170039, FDA–2018–M–2119	Clinical Research Consultants, Inc	CustomFlex™ Artificial Iris	5/30/2018
P910056/S027, FDA–2018–M–2237.	Bausch + Lomb, Inc	enVista® One-Piece Hydrophobic Acrylic Toric Intraocular Lens (Model MX60T).	6/8/2018
P150013/S009, FDA–2018–M–2269.	Dako North America, Inc	PD–L1 IHC 22C3 pharmDx	6/12/2018
P100006/S005, FDA–2018–M–2335.	BioMimetic Therapeutics, LLC	AUGMENT® Injectable	6/12/2018
P170043, FDA–2018–M–2460	Glaukos Corp	iStent *inject* Trabecular Micro-Bypass System (Model G2–M–IS)	6/21/2018

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS AND SAFETY AND PROBABLE BENEFIT SUMMARIES FOR APPROVED HDES MADE AVAILABLE FROM JANUARY 1, 2018, THROUGH SEPTEMBER 18, 2018—Continued

PMA No., Docket No.	Applicant	Trade name	Approval date
P160017/S031, FDA–2018–M–2461.	Medtronic MiniMed, Inc	MiniMed 670G System	6/21/2018
P160048, FDA–2018–M–2463 ..	Senseonics, Inc	Eversense Continuous Glucose Monitoring System	6/21/2018
P180008, FDA–2018–M–2462 ..	Tandem Diabetes Care, Inc	t:slim X2 Insulin Pump with Basal-IQ Technology	6/21/2018
P180002, FDA–2018–M–2571 ..	Pulmonx Corp	Zephyr® Endobronchial Valve System	6/29/2018
P160026, FDA–2018–M–2883 ..	Physio-Control, Inc	LIFEPAK® 1000 Defibrillator, LIFEPAK® 1000 Defibrillator Lithium-Ion Rechargeable Battery, LIFEPAK® 1000 Defibrillator Non-Rechargeable Battery, LIFEPAK® 20 Defibrillator/Monitor (Refurbished), LIFEPAK® 20e Defibrillator/Monitor, LIFEPAK® 15 Monitor/Defibrillator, LIFEPAK® Lithium-ion Rechargeable Battery (for use with the LIFEPAK® 15 Monitor/Defibrillator).	7/2/2018
P170024, FDA–2018–M–2884 ..	Stryker Neurovascular	Surpass Streamline Flow Diverter	7/13/2018
P170041, FDA–2018–M–2885 ..	Abbott Molecular, Inc	Abbott RealTi*me* IDH1	7/20/2018
P160030/S017, FDA–2018–M–2886.	Abbott Diabetes Care Inc	FreeStyle Libre 14 Day Flash Glucose Monitoring System	7/23/2018
P160053, FDA–2018–M–2887 ..	Endomagnetics Ltd	Magtrace™ and Sentimag® Magnetic Localization System	7/24/2018
P170042, FDA–2018–M–2983 ..	C.R. Bard, Inc	COVERA™ Vascular Covered Stent	7/30/2018
P150048/S012, FDA–2018–M–3131.	Edwards Lifesciences LLC	Edwards Pericardial Mitral Bioprosthesis, Model 11000M	8/9/2018
P170034, FDA–2018–M–3153 ..	Ivantis, Inc	Hydrus® Microstent	8/10/2018
P150013/S011, FDA–2018–M–3212.	Dako North America, Inc	PD–L1 IHC 22C3 pharmDx	8/16/2018
P030016/S001, FDA–2018–M–3503.	STAAR Surgical Co	Visian® TORIC ICL (Implantable Collamer® Lens)	9/13/2018
H170004, FDA–2018–M–3505 ..	BIOTRONIK, Inc	PK Papyrus Covered Coronary Stent System	9/14/2018
P180011, FDA–2018–M–3548 ..	Boston Scientific Corp	ELUVIA™ Drug-Eluting Vascular Stent System	9/18/2018

II. Electronic Access

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

Dated: November 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–25071 Filed 11–15–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4002]

Electronic Submission of Adverse Event Reports to the Food and Drug Administration Adverse Event Reporting System Using International Council for Harmonisation E2B(R3) Standards; Public Meetings; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meetings; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing three public meetings entitled ''Electronic Submission of Adverse Event Reports to FDA Adverse Event Reporting System (FAERS) Using International Council for Harmonisation (ICH) E2B(R3) Standards.'' The purpose of these public meetings is to provide the pharmaceutical industry and other interested parties with information on the plans, progress, and technical specifications to upgrade electronic submission standards for drug, biological, and drug/biologic-led combination products for the premarket and postmarket safety surveillance programs managed by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). These meetings will focus on enhancements to electronic submission of Individual Case Safety Reports (ICSRs) in FAERS using ICH E2B(R3) standards.

FDA is seeking input from stakeholders as it fulfills its commitment to implement ICH E2B(R3) standards by holding three public meetings. FDA will use the information provided by the public to inform the enhancements to FAERS required for the implementation of ICH E2B(R3) standards and relevant regional variations.

DATES: The first public meeting will be held on January 25, 2019, from 9 a.m. to 4 p.m. The second public meeting will be held on July 17, 2019, from 9 a.m. to 4 p.m. The third public meeting will be held on February 19, 2020 from 9 a.m. to 4 p.m. Submit either electronic or written comments on these public meetings by February 25, 2019, for the first public meeting; by August 16, 2019, for the second public meeting, and by March 20, 2020, for the third public meeting. See the **SUPPLEMENTARY INFORMATION** section for registration dates and information.

ADDRESSES: Each public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/default.htm*.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. For timely consideration, we request that electronic comments be submitted before or within 30 days after each public meeting (*i.e.,* comments submitted by or before February 25, 2019, for the first public meeting; August 16, 2019, for the second public meeting; and March 20, 2020, for the third public meeting. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 25, 2019; August 16, 2019; and March 20, 2020, after the first, second, and the third meeting, respectively. Comments received by mail/hand