MD 20993–0002, 301–796–7699, email: *PCNS@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Peripheral and Central Nervous System Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases.

The Committee shall consist of a core of nine voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of neurology, neuropharmacology, neuropathology, otolaryngology, epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees, representatives or ex-officio members. Federal members will serve as Regular Government Employees or ex-officio members. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/peripheral-and-central-nervous-system-drugs-advisory-committee/peripheral-and-central-nervous-system-drugs-advisory-committee-charter* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: June 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–12368 Filed 6–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2021–M–0228, FDA–2021–M–0202, FDA–2021–M–0203, FDA–2021–M–0178, FDA–2021–M–0153, FDA–2021–M–0135, FDA–2021–M–0325, FDA–2021–M–0303, FDA–2021–M–0288, FDA–2021–M–0421, FDA–2021–M–0416, FDA–2021–M–0355, FDA–2021–M–0354, FDA–2021–M–0520, FDA–2021–M–0615, FDA–2021–M–0531, FDA–2021–M–0527, FDA–2021–M–0820, FDA–2021–M–0769, FDA–2021–M–0766, FDA–2021–M–0676, FDA–2021–M–0690, FDA–2021–M–0656, FDA–2021–M–0494, FDA–2021–M–0915, FDA–2021–M–0911, FDA–2021–M–0853, FDA–2021–M–0805, FDA–2021–M–1046, FDA–2021–M–1010, FDA–2021–M–0991, FDA–2021–M–0989, FDA–2021–M–0975, FDA–2021–M–0962, FDA–2021–M–1176, FDA–2021–M–1119, FDA–2021–M–1116, FDA–2021–M–0532, FDA–2021–M–1058, FDA–2021–M–1182, FDA–2021–M–1023, FDA–2021–M–1207, FDA–2021–M–1284, FDA–2021–M–1271, FDA–2021–M–1317, FDA–2021–M–1321, FDA–2021–M–1316, FDA–2021–M–1325, FDA–2021–M–1352, FDA–2022–M–0029, FDA–2022–M–0071, FDA–2022–M–0087, FDA–2022–M–0089, FDA–2022–M–0090, and FDA–2022–M–0171].

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 or Agency) is publishing a list of premarket approval applications (PMAs) that have been approved from January 1, 2021, through February 14, 2022. 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. This is the last notice of this kind considering FDA's rule discontinuing the practice of publishing such summaries in the **Federal Register**. As indicated in that rule, FDA will continue to publish to make available on the internet and place on public display summaries of safety and effectiveness for approved PMAs.

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–2021–M–0228, FDA–2021–M–0202, FDA–2021–M–0203, FDA–2021–M–0178, FDA–2021–M–0153, FDA–2021–M–0135, FDA–2021–M–0325, FDA–2021–M–0303, FDA–2021–M–0288, FDA–2021–M–0421, FDA–2021–M–0416, FDA–2021–M–0355, FDA–2021–M–0354, FDA–2021–M–0520, FDA–2021–M–0615, FDA–2021–M–0531, FDA–2021–M–0527, FDA–2021–M–0820, FDA–2021–M–0769, FDA–2021–M–0766, FDA–2021–M–0676, FDA–

2021–M–0690, FDA–2021–M–0656, FDA–2021–M–0494, FDA–2021–M–0915, FDA–2021–M–0911, FDA–2021–M–0853, FDA–2021–M–0805, FDA–2021–M–1046, FDA–2021–M–1010, FDA–2021–M–0991, FDA–2021–M–0989, FDA–2021–M–0975, FDA–2021–M–0962, FDA–2021–M–1176, FDA–2021–M–1119, FDA–2021–M–1116, FDA–2021–M–0532, FDA–2021–M–1058, FDA–2021–M–1182, and FDA–2021–M–1023, FDA–2021–M–1207, FDA–2021–M–1284, FDA–2021–M–1271, FDA–2021–M–1317, FDA–2021–M–1321, FDA–2021–M–1316, FDA–2021–M–1325, FDA–2021–M–1352, FDA–2022–M–0029, FDA–2022–M–0071, FDA–2022–M–0087, FDA–2022–M–0089, FDA–2022–M–0090, and FDA–2022–M–0171 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Dharmesh Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2434, Silver Spring, MD 20993–0002, 301–796–3289, *Dharmesh.Patel@fda.hhs.gov.*

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 published in the **Federal Register**. 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.

Prior to February 14, 2022, the regulations provided that FDA publish a list of available safety and effectiveness summaries of PMA approvals and denials that were announced in the **Federal Register**. FDA issued a rule discontinuing this practice on January 13, 2022 (87 FR 2042). At that time, FDA committed to continue to publish lists of safety and effectiveness summaries of PMA approvals and denials on its website. The following list of approved PMAs for which summaries of safety and effectiveness that were placed on the internet from January 1, 2021, through February 14, 2022, will, therefore, be our last such list to be published in this manner. There were no denial actions during this period. The list in table 1 provides the manufacturer's name, the product's generic name or 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, 2021, THROUGH FEBRUARY 14, 2022

PMA No., docket No.	Applicant	Trade name	Approval date
P200003, FDA–2021–M–0070	Seno Medical Instruments, Inc ...	Imagio® Breast Imaging System	1/11/21
P200028, FDA–2021–M–0135	Medtronic, Inc	DiamondTemp™ Ablation System consisting of DiamondTemp™ AblaDiamondTemp Ablation Catheter (Models CEDT100S, CEDT200L, CEDTB300S, CEDTB400L); DiamondTemp™ RF Generator (Model CEDTG200); DiamondTemp™ Irrigation Pump (Model CEDTP100); DiamondTemp™ Irrigation Tubing Set (Model CEDTTS100); DiamondTemp™ Catheter-to-RF Generator Cable (Model CEDTC100); DiamondTemp™ GenConnect Cable (Model CEDTGC100); DiamondTemp™ EGM Cable (Model CEDTEGM100).	1/28/2021
P140029/S027, FDA–2021–M–0153.	Q-Med AB	Restylane® Defyne	1/29/2021
P190005, FDA–2021–M–0178	Roche Diagnostics	Elecsys Anti-HBe, PreciControl Anti-HBe	2/3/2021
P200039, FDA–2021–M–0202	Shockwave Medical, Inc	Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave C^2 Coronary Intravascular Lithotripsy (IVL) Catheter.	2/12/2021
P190013, FDA–2021–M–0288	AED Battery Exchange, LLC	AED Battery Exchange (Models 9146–ABE, G5–ABE, 5070–ABE, FR3–ABE).	2/13/2021

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, 2021, THROUGH FEBRUARY 14, 2022—Continued

PMA No., docket No.	Applicant	Trade name	Approval date
H200001, FDA–2021–M–0203	Additive Orthopaedics, LLC	Patient Specific Talus Spacer	2/17/2021
P190034, FDA–2021–M–0228	Roche Diagnostics	Elecsys Anti-HBs II, PreciControl Anti-HBs, Anti-HBs CalCheck.	2/23/2021
P200029, FDA–2021–M–0303	Boston Scientific Corporation	TheraSphere™	3/17/2021
P200025, FDA–2021–M–0325	Bausch Health	ClearVisc Ophthalmic Viscosurgical Device (OVD)	3/23/2021
P200046, FDA–2021–M–0354	Medtronic, Inc	Medtronic Harmony Transcatheter Pulmonary Valve (TPV) System.	3/26/2021
P200022/S003, FDA–2021–M–0355.	Simplify Medical, Inc	Simplify® Cervical Artificial Disc	4/1/2021
P200019, FDA–2021–M–0416	Ventana Medical Systems, Inc	VENTANA MMR RxDx Panel	4/22/2021
P980040/S124, FDA–2021–M–0421.	Johnson & Johnson Surgical Vision, Inc.	TECNIS Synergy™ IOL, Model ZFR00V, TECNIS Synergy™ Toric II IOL, Models ZFW150, ZFW225, ZFW300, ZFW375, TECNIS Synergy™ IOL with TECNIS Simplicity™ Delivery System, Model DFR00V, TECNIS Synergy™ Toric II IOL with TECNIS Simplicity™ Delivery System, Model DFW150, DFW225, DFW300, DFW375.	4/28/2021
P200002, FDA–2021–M–0418	AtriCure, Inc	EPi-Sense® Guided Coagulation System	4/28/21
P140031/S125, FDA–2021–M–0473.	Edwards Lifesciences, LLC	Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System.	5/13/21
P200010/S001, FDA–2021–M–0520.	Guardant Health, Inc	Guardant360 CDx	5/21/2021
P110027/S012, FDA–2021–M–0531.	QIAGEN GmbH	therascreen® KRAS RGQ PCR Kit	5/28/2021
P110033/S053, FDA–2021–M–0527.	Allergan	JUVÉDERM® VOLBELLA® XC	5/28/2021
P200010/S002, FDA–2021–M–0494.	Guardant Health, Inc	Guardant360 CDx	5/28/2021
P100010/S110, FDA–2021–M–0690.	Medtronic, Inc	Arctic Front AdvanceTM Cardiac Cryoablation Catheters, Arctic Front Advance ProTM Cardiac Cryoablation Catheters, FreezorTM MAX Cardiac Cryoablation Catheter, CryoConsole Manual Retraction Kit.	6/18/2021
P200021, FDA–2021–M–0615	Oticon Medical	Neuro Cochlear Implant System	6/23/2021
P110019/S115, FDA–2021–M–0656.	Abbott Vascular	XIENCE Alpine Everolimus Eluting Coronary Stent Systems (XIENCE Alpine EECSS), XIENCE Sierra Everolimus Eluting Coronary Stent Systems (XIENCE Sierra EECSS), and the XIENCE Skypoint Everolimus Eluting Coronary Stent Systems (XIENCE Skypoint EECSS).	6/25/2021
P140029/S032, FDA–2021–M–0676.	Q-Med AB, a Galderma affiliate	Restylane® Contour	6/28/2021
P200017, FDA–2021–M–0766	Siemens Healthcare Diagnostics Inc.	ADVIA Centaur® Anti-HBe2 (aHBe2) assay	7/14/2021
P190032/S001, FDA–2021–M–0707.	Foundation Medical, Inc	FoundationOne® Liquid CDx (F1 Liquid)	7/15/21
P130022/S039, FDA–2021–M–0769.	Nervo Corporation	Senza® Spinal Cord Stimulation (SCS) System	7/16/2021
P200037, FDA–2021–M–0820	Kestra Medical Technologies, Inc.	ASSURE® Wearable Cardioverter Defibrillator (WCD) System (ASSURE System).	7/27/2021
P200011, FDA–2021–M–0853	Pillar Biosciences, Inc	ONCO/Reveal™ Dx Lung & Colon Cancer Assay	7/30/2021
P200045, FDA–2021–M–0805	Bolton Medical, Inc	RelayPro Thoracic Stent-Graft System	8/5/2021
P200049, FDA–2021–M–0911	Abbott Medical	Amplatzer™ Amulet™ Left Atrial Appendage Occluder	8/14/2021
P210001, FDA–2021–M–0915	Ventana Medical Systems, Inc	VENTANA MMR RxDx Panel	8/17/2021
P160045/S028, FDA–2021–M–0962.	Life Technologies Corporation	Oncomine® Dx Target Test	8/25/2021
P210007, FDA–2021–M–0991	MicroTransponder Inc	MicroTransponder® Vivistim® Paired VNS™ System (Vivistim® System).	8/27/2021
P050052/S129, FDA–2021–M–0975.	Merz North America, Inc	RADIESSE® (+) Lidocaine injectable implant	9/1/2021
P180051, FDA–2021–M–0989	TransMedics, Inc	Organ Care System (OCS™) Heart System	9/3/2021
P160045/S029, FDA–2021–M–1023.	Life Technologies Corporation	Oncomine™ Dx Target Test	9/15/2021
P190023, FDA–2021–M–1010	Abbott Medical	Portico™ Transcatheter Aortic Valve Implantation System: Portico™ Transcatheter Aortic Heart Valve, FlexNav™ Delivery System, FlexNav™ Loading System.	9/17/2021
P200004, FDA–2021–M–1046	ConMed Corporation	ConMed PadPro Multifunction Electrodes, ConMed PadPro Multifunction Electrode Adapters.	9/26/2021
P200031, FDA–2021–M–1058	TransMedics, Inc	Organ Care System (OCS™) Liver	9/28/2021
P210026, FDA–2021–M–1116	Agilent Technologies, Inc	Ki-67 IHC MIB–1 pharmDx (Dako Omnis)	10/12/2021

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, 2021, THROUGH FEBRUARY 14, 2022—Continued

PMA No., docket No.	Applicant	Trade name	Approval date
P190012, FDA–2021–M–1119	Spatz FGIA Inc	Spatz3 Adjustable Balloon System	10/15/2021
P160046/S010, FDA–2021–M–0532.	Ventana Medical Systems, Inc ...	VENTANA PD–L1 (SP263) Assay	10/15/2021
P150031/S040, FDA–2021–M–1176.	Boston Scientific Corporation	Vercise PC, Vercise Gevia and Vercise Genus DBS Systems.	10/20/2021
P150038/S014, FDA–2021–M–1182.	INSIGHTEC, Inc	Exablate Model 4000 Type 1.0 and 1.1 System (''Exablate Neuro'').	10/29/21
P130026/S070, FDA–2021–M–1207.	Abbott Medical	TactiCath Contact Force Ablation Catheter, Sensor Enabled (Uni-Directional); TactiCath Contact Force Ablation Catheter, Sensor Enabled (Bi-Directional); TactiSys Quartz Equipment; Ampere RF Generator and Cool Point Irrigation Pump.	11/4/21
P210020, FDA–2021–M–1284	Urotronic, Inc	Optilume® Urethral Drug Coated Balloon	12/3/21
P190022, FDA–2021–M–1271	OPKO Health, Inc	4Kscore® Test	12/7/21
P200035, FDA–2021–M–1317	OrganOx Limited	OrganOx metra® System	12/9/21
P210014, FDA–2021–M–1321	Svelte Medical Systems, Inc	SLENDER Sirolimus-Eluting Coronary Stent Integrated Delivery System and DIRECT Sirolimus-Eluting Coronary Stent Rapid Exchange Delivery System.	12/13/21
P200041, FDA–2021–M–1316	OrbusNeich Medical (Shenzhen) Co., Ltd.	Scoreflex NC Scoring PTCA Catheter	12/21/21
P200015/S011, FDA–2021–M–1325.	Edwards Lifesciences LLC	Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent.	12/16/21
P200040, FDA–2021–M–1352	Delphinus Medical Technologies, Inc.	SoftVue Automated Whole Breast Ultrasound System with Sequr Breast Interface Assembly.	10/6/21
P170002/S012, FDA–2022–M–0029.	TEOXANE S.A	RHA® Redensity™	12/22/21
P970051/S205, FDA–2022–M–0071.	Cochlear Americas	Nucleus 24 Cochlear Implant System	1/10/22
P130022/S042, FDA–2022–M–0087.	Nevro Corporation	Senza® Spinal Cord Stimulation (SCS) System	1/18/22
P840001/S469, FDA–2022–M–089.	Medtronic Neuromodulation	Restore, Itrel, Synergy, Intellis, and Vanta Spinal Cord Stimulation Systems, Pisces, Specify and Vectris Spinal Cord Stimulation Leads.	1/21/22
P080012/S068, FDA–2022–M–0090.	Flowonix Medical, Inc	Prometra® Programmable Infusion Pump System	1/12/22
P160048/S016, FDA–2022–M–0171.	Senseonics, Incorporated	Eversense® E3 Continuous Glucose Monitoring System	2/10/22

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: June 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–12371 Filed 6–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: HRSA Ryan White HIV/AIDS Program HIV Quality Measures Module, OMB No. 0906–0022—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than August 8, 2022.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the acting HRSA Information Collection Clearance Officer at (301) 443–9094.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information collection request title for reference.