voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, a non-voting representative of consumer interests and a non-voting representative of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm121602.htm* 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 document 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: May 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10848 Filed 5–21–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–M–3372, FDA–2017–M–3951, FDA–2017–M–3990, FDA–2017–M–4022, FDA–2017–M–4271, FDA–2017–M–4498, FDA–2017–M–4756, FDA–2017–M–4757, FDA–2017–M–4711, FDA–2017–M–4904, FDA–2017–M–5320, FDA–2017–M–5262, FDA–2017–M–5334, FDA–2017–M–5438, FDA–2017–M–5813, FDA–2017–M–5863, FDA–2017–M–5864, FDA–2017–M–5884, FDA–2017–M–5929, FDA–2017–M–5969, FDA–2017–M–5968, FDA–2017–M–5997, FDA–2017–M–6223, FDA–2017–M–6232, FDA–2017–M–6290, FDA–2017–M–6524, FDA–2017–M–6525, FDA–2017–M–6550, FDA–2017–M–6614, FDA–2017–M–6650, FDA–2017–M–6799, FDA–2017–M–6800, and FDA–2017–M–6896]

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 Dockets Management Staff.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: httpss://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–3372, FDA–2017–M–3951, FDA–2017–M–3990, FDA–2017–M–4022, FDA–2017–M–4271, FDA–2017–M–4498, FDA–2017–M–4756, FDA–2017–M–4757, FDA–2017–M–4711, FDA–2017–M–4904, FDA–2017–M–5320, FDA–2017–M–5262, FDA–2017–M–5334, FDA–2017–M–5438, FDA–2017–M–5813, FDA–2017–M–5863, FDA–2017–M–5864, FDA–2017–M–5884, FDA–2017–M–5929, FDA–2017–M–5969, FDA–2017–M–5968, FDA–2017–M–5997, FDA–2017–M–6223, FDA–2017–M–6232, FDA–2017–M–6290, FDA–2017–M–6524, FDA–2017–M–6525, FDA–2017–M–6550, FDA–2017–M–6614, FDA–2017–M–6650, FDA–2017–M–6799, FDA–2017–M–6800, and FDA–2017–M–6896 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 July 1, 2017, through December 31, 2017. 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 JULY 1, 2017, THROUGH DECEMBER 31, 2017

PMA No., Docket No.	Applicant	Trade name	Approval date
P160015, FDA–2017–M–3372	Zoll Medical Corporation	AED Plus® and Fully Automatic AED Plus®	5/26/2017
P970003/S207, FDA–2017–M–3951.	Cyberonics, Inc	VNS Therapy System	6/23/2017
P150048, FDA–2017–M–3990	Edwards Lifesciences, LLC	Edwards Pericardial Aortic Bioprosthesis and Edwards INSPIRIS RESILIA Aortic Valve.	6/29/2017
P930016/S048, FDA–2017–M–4022.	AMO Manufacturing USA, LLC	STAR S4 IR Excimer Laser System and iDesign Advanced WaveScan Studio System.	6/30/2017
P130021/S033, FDA–2017–M–4271.	Medtronic CoreValve LLC	Medtronic CoreValve™ System, Medtronic CoreValve™ Evolut™ R System and Medtronic CoreValve™ Evolut™ PRO Systems.	7/10/2017
P160049, FDA–2017–M–4498	Spectranetics Corp	Stellarex 0.035″ OTW Drug-coated Angioplasty Balloon	7/26/2017
P170006, FDA–2017–M–4756	Medtronic, Inc	Avalus™ Bioprosthesis	7/31/2017
P170005, FDA–2017–M–4757	Abbott Molecular, Inc	Abbott RealTi*m*e IDH2	8/1/2017
P160042, FDA–2017–M–4711	Prollenium Medical Technologies, Inc.	Ravanesse Ultra	8/4/2017
P030017/S275, FDA–2017–M–4904.	Boston Scientific Neuromodulation Corporation.	Precision™ Spinal Cord Stimulator System, Precision Spectra™ Spinal Cord Stimulator System, Precision™ Novi™ Spinal Cord Stimulator System, Precision™ Montage™ MRI Spinal Cord Stimulator System, Precision™ Montage™ Spinal Cord Stimulator System and Spectra WaveWriter™ Spinal Cord Stimulator System.	8/11/2017
P160054, FDA–2017–M–5320	Thoratec Corporation	HeartMate 3™ Left Ventricular Assist System	8/23/2017
P140015/S020, FDA–2017–M–5262.	Tandem Diabetes Care, Inc	t:slim X2 Insulin Pump with Dexcom G5 Mobile CGM	8/25/2017
P170003, FDA–2017–M–5334	Lutonix, Inc	Lutonix® 035 Drug Coated Balloon PTA Catheter, Model 9010.	8/25/2017
P170007, FDA–2017–M–5438	Bioventus LLC	DUROLANE®	8/29/2017
P150025/S003, FDA–2017–M–5813.	Dako North America, Inc	PD–L1 IHC 28–8 pharmDx	9/15/2017
P150042, FDA–2017–M–5863	ZEUS Scientific, Inc	ZEUS ELISA Parvovirus B19 IgM Test System	9/19/2017
P150045, FDA–2017–M–5864	ZEUS Scientific, Inc	ZEUS ELISA Parvovirus B19 IgG Test System	9/19/2017
P170011, FDA–2017–M–5884	ABIOMED, Inc	Impella RP® System	9/20/2017
P150013/S006, FDA–2017–M–5929.	Dako North America, Inc	PD–L1 IHC 22C3 pharmDx	9/22/2017
P160030, FDA–2017–M–5969	Abbott Diabetes Care, Inc	Freestyle Libre Flash Glucose Monitoring System	9/27/2017
P100047/S090, FDA–2017–M–5968.	Medtronic, Inc	HeartWare™ HVAD™ System	9/27/2017
P100021/S063, FDA–2017–M–5997.	Medtronic Vascular	Endurant II/Endurant IIs Stent Graft System	9/29/2017
P160039, FDA–2017–M–6223	Respicardia, Inc	remedē® System	10/6/2017
P170002, FDA–2017–M–6232	Teoxane S.A	RHA® 2, RHA® 3 and RHA® 4	10/19/2017
P150028/S001, FDA–2017–M–6290.	NuMED, Inc	Cheatham Platinum (CP) Stent System (Covered CP Stent, Model 427; Covered Mounted (CP) Stent, Model 428; CP Stent, Model 425; Mounted CP Stent, Model 426).	10/24/2017
H020002/S046, FDA–2017–M–6524.	Stryker Neurovascular	Neuroform Atlas™ Stent System	11/2/2017
P160057, FDA–2017–M–6525	OrthogenRx, Inc	TriVisc	11/13/2017
P160043/S001, FDA–2017–M–6550.	Medtronic Vascular	Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	11/16/2017
P160055, FDA–2017–M–6614	RxSight, Inc	Light Adjustable Lens (LAL) and Light Delivery Device (LDD)	11/22/2017
P170008, FDA–2017–M–6650	Medinol Ltd	EluNIR® Ridaforolimus Eluting Coronary Stent System	11/28/2017
P170019, FDA–2017–M–6799	Foundation Medicine, Inc	FoundationOne CDx	11/30/2017

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JULY 1, 2017, THROUGH DECEMBER 31, 2017—Continued

PMA No., Docket No.	Applicant	Trade name	Approval date
P150031, FDA–2017–M–6800	Boston Scientific Corporation	Vercise Deep Brain Stimulation (DBS) System	12/8/2017
P170012, FDA–2017–M–6896	Biom'Up SA	HEMOBLAST™ Bellows	12/15/2017

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: May 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10924 Filed 5–21–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1820]

Framework for Assessing pH-Dependent Drug-Drug Interactions; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to assist with the development of a policy or guidance document on the assessment of pH-dependent drug-drug interactions (DDIs). In October 2017, FDA published two draft guidance documents on DDIs entitled ''In Vitro Metabolism- and Transporter-Mediated Drug-Drug Interaction Studies'' (In Vitro Studies Draft Guidance) and ''Clinical Drug Interaction Studies—Study Design, Data Analysis, and Clinical Implications'' (Clinical Drug Interaction Studies Draft Guidance). These two draft guidances focus on enzyme- and transporter-based DDIs and do not include a framework to assess pH-dependent DDIs. FDA is seeking public input on best practices in the planning and evaluation of pH-dependent DDIs.

DATES: Submit either electronic or written comments on this notice by July 23, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 23, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of July 23, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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 No. FDA–2018–N–1820 for ''Framework for Assessing pH-dependent Drug-Drug Interactions; Establishment of Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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