

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Invitation: Young Adults (Ages 18–25) .....	29,000	1	29,000	0.02 (1 minute) .....	580
Invitation: Adults (Ages 26+) .....	29,000	1	29,000	0.02 (1 minute) .....	580
Consent and Screener: Young Adults (Ages 18–25) .....	11,000	1	11,000	0.10 (6 minutes) .....	1,100
Consent and Screener: Adults (Ages 26+) .....	16,500	1	16,500	0.10 (6 minutes) .....	1,650
Study: Young Adults (Ages 18–25) .....	3,300	1	3,300	0.33 (20 minutes) .....	1,089
Study: Adults (Ages 26+) .....	3,300	1	3,300	0.33 (20 minutes) .....	1,089
Total .....					6,088

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

FDA's burden estimate is based on prior experience with research that is similar to this proposed study. Approximately 58,000 people will receive a study invitation, estimated to take 1 minute to read (approximately 0.02 hour), for a total of 1,160 hours for invitations. Approximately 27,500 people will complete the informed consent and screener to determine eligibility for participation in the study, estimated to take 6 minutes (0.10 hour), for a total of 2,750 hours for informed consent and screening activities. Approximately 6,600 people will complete the full study, estimated to take 20 minutes (approximately 0.33 hour), for a total of 2,178 hours for study completion activities. The estimated total hour burden of the collection of information is 6,088 hours.

## II. References

The following references marked with an asterisk (\*) are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Tormala, Z.L. and D.D. Rucker, "Attitude Certainty: A Review of Past Findings and Emerging Perspectives." *Social and Personality Psychology Compass*, 1:469–492, 2007. doi:10.1111/j.1751-9004.2007.00025.x.
2. Tormala, Z.L. and D.D. Rucker, "Attitude Certainty: Antecedents, Consequences,

and New Directions." *Consumer Psychology Review*, 1:72–89, 2018. doi:10.1002/arcp.1004.\*

Dated: October 23, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–23523 Filed 10–26–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2018–N–1726]

### Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

**DATES:** The meeting will be held on December 4 and 5, 2018, from 8 a.m. to 6 p.m.

**ADDRESSES:** Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel telephone number is 301–977–8900; additional information available online at: <https://www3.hilton.com/en/hotels/maryland/hilton-washington-dc-north-gaithersburg-GAIGHHF/index.html>.

Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/>

*AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm*.

### FOR FURTHER INFORMATION CONTACT:

Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G610, Silver Spring, MD 20993–0002, [patricio.garcia@fda.hhs.gov](mailto:patricio.garcia@fda.hhs.gov), 301–796–6875, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

### SUPPLEMENTARY INFORMATION:

**Agenda:** On December 4, 2018, the committee will discuss, make recommendations, and vote on information regarding the premarket application (PMA) for the OPTIMIZER SMART Implantable Pulse Generator device, sponsored by Impulse Dynamics (USA), Inc. This first-of-a-kind device is indicated to provide cardiac contractility modulation for class III heart failure patients who are not responding to optimal medical therapy.

On December 5, 2018, the committee will discuss and make recommendations regarding issues relating to the emergence of medical devices, which aim to treat hypertension. Currently, clinical studies to evaluate the safety and effectiveness of these devices are progressing. FDA requests panel input regarding the potential indications and labeling for devices intended to treat hypertension and optimal study designs needed to

evaluate the potential benefits and risks while considering issues such as medication compliance, patient perspective, and appropriate study controls.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

**Procedure:** FDA will work with affected industry, professional organizations, and societies with an interest in medical devices designed to treat hypertension, as well as members of those groups who wish to make a presentation separate from the general open public hearing; time slots are available on December 5, 2018. Representatives from industry, professional organizations and societies interested in making formal presentations to the committee should notify the contact person on or before November 13, 2018.

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 21, 2018. Oral presentations from the public will be scheduled on December 4 and 5, between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 13, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 14, 2018.

Persons attending FDA's advisory committee meetings are advised that the

Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at [artair.mallett@fda.hhs.gov](mailto:artair.mallett@fda.hhs.gov) or 301-796-9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 24, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-23577 Filed 10-26-18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-E-4181]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; RAINDROP NEAR VISION INLAY

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for RAINDROP NEAR VISION INLAY and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

**DATES:** Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by December 28, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by

April 29, 2019. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**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 December 28, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 28, 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-2017-E-4181 for "Determination of