[4] The reporting requirements under §§ 601.12(a)(2) and (b)(4), 600.15(b), 610.9(a), 610.53(d), 606.110(b), 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), 640.120, and 680.1(d) are included in the estimate under § 601.12(b).
[5] The reporting requirements under §§ 601.12(a)(2), 610.9(a), 640.17, 640.25(c), 640.56(c), and 640.74(b)(2) are included in the estimate under § 601.12(c).
[6] The reporting requirement under § 601.12(a)(2) is included in the estimate under § 601.12(d).
[7] The reporting requirement under § 601.14 is included in the estimate under § 601.12(f)(1) and (2).
[8] The reporting requirement under §§ 601.12(a)(4) and 601.14 is included in the estimate under § 601.12(f)(3).
[9] The reporting requirement under § 601.94 is included in the estimate under § 601.45.
[10] The numbers in this column have been rounded to the nearest whole number.

Under table 2, the estimated recordkeeping burden of 1 hour is based on previous estimates for the recordkeeping requirements associated with the AER system.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

| 21 CFR section | Number of respondents | Annual disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours [2] |
|---|---|---|---|---|---|
| 601.6(a) | 1 | 20 | 20 | 0.33 (20 minutes) | 7 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Rounded to the nearest whole number.

Dated: July 5, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–16352 Filed 7–8–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–N–0001]**

### Controlling the Progression of Myopia: Contact Lenses and Future Medical Devices; Public Workshop

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

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA), in cosponsorship with the American Academy of Ophthalmology (AAO), American Academy of Optometry (AAOpt), American Association for Pediatric Ophthalmology and Strabismus (AAPOS), American Optometric Association (AOA), American Society of Cataract and Refractive Surgery (ASCRS), and Contact Lens Association of Ophthalmologists, Inc. (CLAO) is announcing a public workshop entitled ''Controlling the Progression of Myopia: Contact Lenses and Future Medical Devices.'' The purpose of this workshop is to discuss the increasing prevalence of myopia, as well as suggested clinical trial design attributes for studies using contact lenses or other medical devices to control the progression of myopia.

**DATES:** The public workshop will be held on September 30, 2016, from 8 a.m. to 6 p.m. Pickup of materials will begin at 7:30 a.m.

**ADDRESSES:** The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, the Great Room, (Rm. 1503), Silver Spring, MD, 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

**FOR FURTHER INFORMATION CONTACT:** Michelle Tarver, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2504, Silver Spring, MD 20993, 301–796–6884.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

The prevalence of myopia in the United States has increased over the past decade with approximately 24 percent (over 30 million) of adults over 40 years of age being affected. Recent studies have found the overall prevalence of myopia to be 1.2 percent among non-Hispanic White children, 6.6 percent in African Americans, 3.7 percent in Hispanic, and 3.98 percent in Asian children. Pathologic myopia is the third most frequent cause of blindness due to retinal detachments or abnormal blood vessel growth. Given these potentially poor outcomes with high myopia, researchers have sought ways to prevent its development by starting interventions in childhood. The literature suggests that myopia progression is most rapid between 6 and 11 years of age and manipulating peripheral retinal image quality may be a treatment strategy to control axial length and therefore the progression of myopia. The results of studies conducted with specialized contact lenses, both rigid and soft, have indicated that this approach may reduce the rate of myopic progression in children. As research into myopia control is continuing at a rapid pace, accompanying potential safety and effectiveness questions also have emerged. To ensure that the studies conducted provide information that can adequately inform the regulatory review, we are conducting a workshop to answer questions about the appropriate clinical trial design and outcomes for these devices.

#### II. Topics for Discussion at the Public Workshop

Topics to be discussed at the public workshop include, but are not limited to the following topics:

- Myopia Demographics.
- Contact Lens Use and Safety in a Pediatric Population.
- Contact Lens Behaviors and Hygiene.
- Studies Conducted on Myopia Control Devices and Their Challenges.
- Regulation of Contact Lenses (Ref. 1).
- Patient/Caregiver Perspectives and the Role in Trial Design and Conduct (Refs. 2 and 3).

We will also have a panel discussion to address questions related to the design of these clinical trials.

*Registration:* Registration is $250 for members of AAO, AAOpt, AAPOS, AOA, ASCRS, or CLAO; and $400 for non-members and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online. The deadline for online registration is September 23, 2016, at 4 p.m. EDT. There will be no onsite registration on the day of the public workshop. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization.

If you need special accommodations due to a disability, please contact Ms. Susan Monahan at *susan.monahan@fda.hhs.gov* or 301–796–5661 no later than September 16, 2016.

To register for the public workshop, please visit *http://www.cfom.info/meetings/myopia/.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, telephone number, and membership in the cosponsoring organizations. If there are any questions with registration, please contact Mrs. Bobbi Hahn at *bhahn@cfom.info.* Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Food may be purchased in advance for $45 on the registration Web site (*http://www.cfom.info/meetings/myopia/*). Food and beverages will also be available for purchase by participants during the workshop breaks.

For more information on the workshop, please see the FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Those without Internet access should contact Bobbi Hahn to register at 651–731–7257.

*Streaming Webcast of the Public Workshop:* The public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by September 23, 2016. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after September 23, 2016. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

*Transcripts:* Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.* A link to the transcript will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

## III. References

The following references are on display in the Division of Dockets Management (see *Transcripts*) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses. U.S. Department of Health and Human Services, Food and Drug Administration. May 1994. *http://www.fda.gov/RegulatoryInformation/Guidances/ucm080928.htm.*
2. Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. U.S. Department of Health and Human Services, Food and Drug Administration. December 2009. *http://www.fda.gov/downloads/Drugs/.../Guidances/UCM193282.pdf.*
3. Draft Guidance: Patient Preference Information—Submission, Review in PMAs, HDE Applications, and *De Novo* Requests, and Inclusion in Device Labeling. U.S. Department of Health and Human Services, Food and Drug Administration. Posted March 2015. *http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm446680.pdf.*

Dated: July 6, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–16353 Filed 7–8–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–D–3787]**

### Information To Support a Claim of Electromagnetic Compatibility of Electrically-Powered Medical Device; Guidance for Industry and Food and Drug Administration Staff; Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Device.'' This guidance describes the types of information that should be provided to support a claim of EMC in a premarket submission for an electrically powered medical device. Electromagnetic disturbance is electronic product radiation that may interfere with the performance of an electrically powered medical device in its intended environment (*i.e.,* cause an electromagnetic interference (EMI)). EMC assessment helps to ensure that a device is able to function in its intended environment without introducing excessive electromagnetic disturbances that might interfere with other devices.

**DATES:** Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

**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,