

FDA estimates that approximately 400 firms (“number of respondents” in table 1) distribute scientific and medical publications that discuss unapproved new uses for FDA-approved or -cleared products. FDA also estimates that each firm would include some or all of the

additional information described previously when distributing annually a total of approximately 40,000 scientific or medical journal articles, scientific or medical reference texts, or CPGs (“total annual disclosures” in table 1) that discuss unapproved new uses for FDA-

approved or -cleared products. FDA estimates that it will take each firm approximately 4 hours (“hours per disclosure” in table 1) to make the disclosures recommended in this draft guidance.

TABLE 1—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN ¹

Draft guidance on distributing scientific and medical information on unapproved new uses	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Distribution of scientific and medical information on unapproved new uses	400	100	40,000	4	160,000

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

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>, or <http://www.regulations.gov>.

Dated: February 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public. The meeting of the Ophthalmic Devices Panel Advisory Committee scheduled for February 14, 2014, was postponed due to unanticipated weather conditions and rescheduled for March 14, 2014.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA’s regulatory issues.

Date and Time: The meeting will be held on March 14, 2014, from 8 a.m. to 6 p.m. This meeting is being rescheduled because of a postponed meeting announced in the **Federal Register** of December 24, 2013 (78 FR 77688), originally scheduled for February 14, 2014.

Location: Hilton Washington, DC/ North, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel’s phone number is 301-977-8900.

Contact Person: Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20933, 301-796-5920, Natasha.Facey@fda.hhs.gov, 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 Web site at <http://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.

Agenda: On March 14, 2014, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application for the Visian Toric Implantable Collamer Lens (TICL) sponsored by STAAR Surgical Company. “Visian TICL proposed indications for use:

- For adults 21–45 years of age;
- For correction of myopic astigmatism in adults with spherical equivalent ranging from -3.0D to ≤ -15.0D with cylinder of 1.0D to 4.0D;
- For the reduction of myopic astigmatism in adults with spherical equivalent ranging from greater than -15.0D to -20.0D with cylinder 1.0D to 4.0D;
- With an anterior chamber depth (ACD) of 3.0 mm or greater, when measured from the corneal endothelium to the anterior surface of the crystalline lens and a stable refractive history (within 0.5 Diopter for 1 year prior to implantation); and
- The Visian TICL is intended for placement in the posterior chamber (ciliary sulcus) of the phakic eye.”

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 Web site 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 Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: 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 March 7, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on March 14, 2014. 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 February 27, 2014. 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 March 3, 2014.

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 physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams at Annmarie.Williams@fda.hhs.gov or 301-796-5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://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: February 25, 2014.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Risk Communications Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Risk Communications Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 5 and 6, 2014, from 9 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." 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 <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Contact Person: Luis G. Bravo, Risk Communication Staff, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3274, Silver Spring, MD 20993-0002, 240-402-5274, email Luis.Bravo@fda.hhs.gov, 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 Web site at <http://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.

If you are unable to join us in person, we encourage you to watch the free Web cast. Visit the Risk Communication Advisory Committee Web site at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/default.htm>. The link will become active shortly before the open session begins at 9 a.m.

Agenda: On May 5 and 6, 2014, the committee will meet to discuss methods for identifying the impact and increasing the reach of communications on topics of interest to consumers. The discussion will also address how FDA can evaluate whether its Consumer Updates (<http://www.fda.gov/ForConsumers/ConsumerUpdates/default.htm>) are reaching the targeted population, and whether they are increasing awareness and understanding of the key risk messages. The discussion will also assess whether the communications are having the intended impact on knowledge, behaviors and/or outcomes.

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 Web site 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 Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: 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 April 28, 2014. Oral presentations from the public will be scheduled 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 April 18, 2014. 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