Dated: February 26, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–04613 Filed 2–28–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0053]

Revised Draft Guidance for Industry on Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled ''Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices.'' This draft guidance revises the final guidance titled ''Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices'' published in January 2009. The revised draft guidance provides guidance on FDA's current thinking on recommended practices for drug or medical device manufacturers and their representatives to follow when distributing to health care professionals or health care entities scientific or medical journal articles, scientific or medical reference texts, or clinical practice guidelines ((CPGs); all three collectively referred to as ''scientific and medical publications'') that discuss unapproved new uses for approved drugs or approved or cleared medical devices marketed in the United States.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 2, 2014. Submit either electronic or written comments on the proposed collection of information by May 2, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448; or to the Division of Small Manufacturers, International and Consumer Assistance, Office of Communication, Education and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding prescription drugs: Bryant Godfrey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 51, Rm. 3258, Silver Spring, MD 20993–0002, 301–796–1200.

Regarding prescription biological products: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

Regarding medical devices: Deborah Wolf, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3414, Silver Spring, MD 20993–0002, 301–796–5732.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices.'' This draft guidance describes recommended practices for drug or medical device manufacturers or their representatives to follow when distributing to health care professionals or health care entities scientific and medical publications that discuss unapproved new uses of approved drugs or approved or cleared medical devices.

In January 2009, FDA published a final guidance titled ''Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices,'' which set forth the Agency's thinking as of that time regarding the dissemination by manufacturers of medical journal articles and scientific or medical reference publications that discuss unapproved or uncleared uses of medical products.[1] FDA received comments to the docket for the 2009 guidance, including submissions requesting clarification of how the principles set forth in the 2009 guidance would apply to medical textbooks and potential changes to those principles.

In July 2011 and September 2013, FDA received citizen petitions, filed on behalf of multiple prescription drug and medical device manufacturers, that include several requests related to FDA's approach to the distribution of scientific and medical information reflecting unapproved or uncleared uses, specifically including CPGs.[2] FDA continues to consider the specific requests made in the citizen petitions, which include requests for issuance or revision of regulations, and has not yet reached a final determination on those petitions.

At the same time, FDA continues actively to review, analyze, and develop approaches to a variety of topics of interest to industry and others, including issues raised in the petition. As part of this process, FDA is soliciting public comment on the draft guidance made available here. Similarly, as part of the Agency's ongoing efforts to address industry questions, FDA continues to solicit public input and consider approaches with respect to several related issues, including the following:

(1) *Further explaining ''scientific exchange.''* On December 28, 2011, FDA issued a **Federal Register** notice (76 FR 81508) opening a docket and requesting comments and information related to ''scientific exchange.'' Comments were submitted to Docket No. FDA–2011–N–0912. FDA is reviewing those comments and considering how that information may inform future Agency action related to its policies on communications and activities related to unapproved or uncleared uses of marketed drugs and devices, as well as communications and activities related to use of products that are not yet legally marketed for any use.

[1] Please visit *http://www.regulations.gov* and enter docket number FDA–2008–D–0053.

[2] Please visit *http://www.regulations.gov* and enter docket numbers FDA–2011–P–0512 and FDA–2013–P–1079.

(2) *Developing guidance on the issue of manufacturer responses to unsolicited requests for information relating to unapproved or uncleared uses.* In December 2011, FDA issued a draft guidance entitled ''Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices.'' FDA is currently considering comments on that draft guidance to inform its further action on this topic.

(3) *Considering draft guidance on industry interactions with formulary committees, payors, and similar entities.* This includes clarifying the Agency's interpretation of several terms included in section 114 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) and the Agency's recommendations for evidentiary support for health care economic information included in promotional materials disseminated to formulary committees and similar entities.

Among the other issues under evaluation, FDA is considering a range of options for responding to questions about industry participation in scientific discussions and for addressing industry dissemination of new scientific information related to approved or cleared uses of marketed drugs and devices.

FDA is soliciting public comment on the revised draft guidance made available here, which presents recommended practices for drug or medical device manufacturers and their representatives to follow if they choose to distribute to health care professionals or health care entities scientific or medical journal articles, scientific or medical reference texts, or CPGs that discuss unapproved or uncleared uses of legally marketed drugs and devices. If the recommended practices are followed, FDA does not intend to use distribution of these publications as evidence of the manufacturer's intent that the product be used for an unapproved new use. FDA is issuing the revised guidance in draft form to enable the public to provide comments on the proposed recommendations.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115) and, when finalized, will represent the Agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices.

Description of Respondents: Respondents to this collection of information are manufacturers and distributors (firms) of approved drug products or approved/cleared medical devices.

Burden Estimate: The draft guidance pertains to the distribution of scientific and medical publications by FDA-regulated industry that discuss unapproved new uses for approved or cleared products. The draft guidance explains that FDA's current position is that if a manufacturer follows the recommendations as described in the draft guidance, FDA does not intend to use the distribution of the scientific and medical publications as evidence of intent that the product be used for an unapproved new use. Because the draft guidance recommends that scientific and medical publications reflecting unapproved or uncleared uses that are distributed have certain characteristics, and that certain other information be distributed with them, the guidance recommends a ''third-party disclosure'' that constitutes a ''collection of information'' under the PRA.

The draft guidance provides recommendations regarding the characteristics of scientific and medical publications that companies may choose to distribute. Elaborated in more detail in the draft guidance, these characteristics in general include that these publications be from journals, scientific or medical reference texts, and CPGs that are produced by independent sources and meet criteria for professional/peer review; be based on specified types of scientific evidence; and be complete, unabridged, and without highlighting or characterization by the manufacturer. In addition, the draft guidance provides recommendations for additional information to be supplied with the publications.

Specifically, the draft guidance recommends the following:

Scientific or medical journal articles should:

- Be disseminated with the approved labeling or, in the case of a medical device reviewed under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), labeling for the indications in the product's cleared indications for use statement, for each of the manufacturer's products that is included in the distributed article.
- Be disseminated with a comprehensive bibliography, when such information exists, of publications discussing adequate and well-controlled clinical studies published in scientific journals, medical journals, or scientific texts about the use of the drug or medical device covered by the information disseminated (unless the information already includes such a bibliography).
- Be disseminated with a representative publication, when such information exists, that reaches contrary or different conclusions regarding the unapproved use—especially when the conclusions of articles to be disseminated have been specifically called into question by another publication.
- Be accompanied by a prominently displayed and permanently affixed statement disclosing:
  - The drug(s) or device(s) included in the journal reprint in which the manufacturer has an interest;
  - That some or all uses of the manufacturer's drugs or devices described in the information have not

been approved or cleared by FDA, as applicable to the described drug(s) or device(s);

○ Any author known to the manufacturer as having a financial interest in the manufacturer or in a product of the manufacturer that is included in the journal article, or who is receiving compensation from the manufacturer, along with the affiliation of the author, to the extent known by the manufacturer, and the nature and amount of any such financial interest of the author or compensation received by the author from the manufacturer;

○ Any person known to the manufacturer who has provided funding for the study;

○ All significant risks or safety concerns associated with the unapproved use(s) of the manufacturer's product(s) discussed in the journal article that are known to the manufacturer but not discussed in the journal article.

Scientific or medical reference texts should:

• When distributed in their entirety by a manufacturer:

○ Contain a prominently displayed and permanently affixed statement identifying the distributing manufacturer and disclosing that some of the uses for drugs and/or devices described in the reference text might not be approved or cleared by FDA. The statement should also disclose that the author(s) of some chapters also might have a financial interest in the manufacturer or its products, unless the manufacturer has verified that none of the authors for the reference text has a financial interest in the manufacturer or a product being written about.[3] This statement should be placed by sticker, stamp, or other similar means on the front cover of the textbook;

○ In situations where a reference text is distributed in its entirety but one or more individual chapters of that reference text devote primary substantive discussion to an individual product or products of the manufacturer distributing it, be disseminated with the approved product labeling for each such product or, in the case of a medical device reviewed under section 510(k) of the FD&C Act, labeling for the indications in the product's cleared indications for use statement.

• If, in lieu of an entire scientific or medical reference text, a manufacturer distributes an individual chapter(s) that includes information on unapproved/uncleared uses of the manufacturer's product(s), the chapter(s) should:

○ When necessary to provide context, be disseminated with other unaltered/unabridged chapters extracted directly from the same scientific or medical reference text, such as chapters which provide related or supportive information;

○ Contain a prominently displayed and permanently affixed statement identifying the distributing manufacturer and disclosing: (1) The drug(s) or device(s) addressed in the individual chapter(s) in which the manufacturer has an interest; (2) that some or all uses of the manufacturer's drugs and/or devices described in the ensuing information have not been approved or cleared by FDA, as applicable to the described drug(s) or medical device(s); (3) any author known to the manufacturer as having a financial interest in the manufacturer or in a product of the manufacturer that is included in the individual chapter(s), or who is receiving compensation from the manufacturer, along with the affiliation of the author, to the extent known by the manufacturer, and the nature and amount of any such financial interest of the author or compensation received by the author from the manufacturer; and (4) all significant risks or safety concerns associated with the unapproved use(s) of the manufacturer's products discussed in the individual chapter(s) that are known to the manufacturer but not discussed in the chapter(s);

○ Be disseminated with the approved labeling, or, in the case of a medical device reviewed under section 510(k) of the FD&C Act, labeling for the indications in the cleared indications for use statement, for each of the manufacturer's products that are included in the distributed chapter(s).

CPGs should:

• When distributed by a manufacturer in their entirety:

○ Contain a prominently displayed and permanently affixed statement identifying the distributing manufacturer and disclosing that some of the uses of drugs and/or devices described in the CPG might not be approved or cleared by FDA. The statement should also disclose that the author(s) of some sections might have a financial interest in the manufacturer or its products, unless the manufacturer has verified that none of the authors for the CPG has a financial interest in the manufacturer or a product being written about. This statement should be placed by sticker, stamp, or other similar means on the front page of the CPG.

○ In situations where a CPG is distributed in its entirety but one or more individual sections of that CPG devotes primary substantive discussion to an individual product or products of the manufacturer distributing it, be disseminated with the approved product labeling for each such product or, in the case of a medical device reviewed under section 510(k) of the FD&C Act, labeling for the indications in the product's cleared indications for use statement.

• If, in lieu of an entire CPG, a manufacturer distributes an individual section(s) that includes information on unapproved/uncleared uses of the manufacturer's product(s), the section(s) should:

○ When necessary to provide context, be disseminated with other unaltered/unabridged sections extracted directly from the same CPG, such as sections which provide related or supportive information;

○ Contain a prominently displayed and permanently affixed statement identifying the distributing manufacturer and disclosing: (1) The drug(s) or device(s) addressed in the individual section(s) in which the manufacturer has an interest; (2) that some or all uses of the manufacturer's drugs and/or devices described in the attached information have not been approved or cleared by FDA, as applicable to the described drug(s) or medical device(s); (3) any author known to the manufacturer as having a financial interest in the manufacturer or in a product of the manufacturer that is included in the individual section(s), or who is receiving compensation from the manufacturer, along with the affiliation of the author, to the extent known by the manufacturer, and the nature and amount of any such financial interest of the author or compensation received by the author from the manufacturer; and (4) all significant risks or safety concerns associated with the unapproved use(s) of the manufacturer's products discussed in the individual section(s) that are known to the manufacturer but not discussed in the section(s).

○ Be disseminated with the approved labeling, or, in the case of a medical device reviewed under section 510(k) of the FD&C Act, labeling for the indications in the cleared indications for use statement, for each of the manufacturer's products that is included in the distributed section(s).

[3] If a reference text is distributed in its entirety with this statement affixed, manufacturers are not expected to have reviewed every element of the reference text to identify discussions of off-label uses of their products. However, even where an entire reference text is being distributed, manufacturers should determine whether one or more individual chapters of that reference text devote primary substantive discussion to an individual product or products of the manufacturer distributing it, in order to determine whether dissemination of product labeling is recommended.

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.

[FR Doc. 2014–04560 Filed 2–28–14; 8:45 am]

BILLING CODE 4160–01–P

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