DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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July 20, 2007

Michael Patterson, Ph.D., BSEE
1866 Castleway Lane
Atlanta, Georgia 30345

Re:
1. **2006P-0212**, filed May 17, 2006 (CP 1)
2. **2006P-0213**, filed May 17, 2006 (CP 2)
3. **2006P-0518**, filed December 18, 2006 (CP 3)
4. **2006P-0519**, filed December 18, 2006 (CP 4)

Dear Dr. Patterson:

This letter responds to the four above referenced citizen petitions that you submitted to the Food and Drug Administration (FDA or the agency). Each petition seeks to challenge the current regulatory status, review procedures, and enforcement policies regarding medical devices used in laser-assisted *in situ* keratomileusis (LASIK) surgery, as well as medical devices used in phakic intraocular lens (PIOL) implantation. Your petitions request that: the Commissioner of Food and Drugs place moratoriums on the use of, and rescind the approval of, certain currently approved medical devices used in these procedures; FDA convene a meeting of its Ophthalmic Devices Advisory Panel (the panel) to consider research used in support of pending and existing device approvals, most particularly refractive lasers for LASIK, microkeratomes, and PIOL; the agency impose penalties for alleged violations of Institutional Review Board (IRB) protocols during certain LASIK and PIOL research studies; FDA develop a national agenda for the prevention of injuries from elective refractive eye surgery and to collect information on the cost-effectiveness of strategies that would serve to reduce such injuries; and that FDA improve or enhance its biomedical research monitoring and compliance programs, with specific attention to the off-label use of certain devices, the purported illegal re-use of single-use-devices (SUDs) used in LASIK surgery, and the possible lack of adherence by physicians to adequately obtaining informed consent from patients.

As you may already be aware, the agency's Center for Devices and Radiological Health (CDRH) is responsible for evaluating the safety and effectiveness, along with the accompanying labeling, of medical devices used in LASIK surgery and PIOL implantation. While we believe that the current regulations provide adequate assurance of the safety and effectiveness of devices when used according to their labeling, it is CDRH's practice to convene a team of experts to assess the postmarket experience of particular device(s) upon receiving information suggesting adverse events that are unanticipated or occurring at an unexpected rate. Accordingly, CDRH convened a team to evaluate the postmarket data on quality-of-life (QOL) following LASIK,

2006P-0212

PDN 1

including the issues you have identified in your numerous calls, e-mails, and subsequent petitions to the agency.

In support of your petitions, you cite a number of individual case reports, personal experiences, and third-party testimonials, and you offer informal scientific analysis. You also incorporate by reference various pieces of information obtained from the Internet and other sources that you believe provide a basis for the actions you request. These kinds of incorporation by reference are not accepted as support for a petition under 21 CFR Part 10.20(c), primarily because they cannot be verified in light of the constantly changing information on websites. Nevertheless, FDA has reviewed all the claims in each of your petitions, as well as the statements and references you provide to support your conclusions. As discussed in greater detail below, your petitions are granted in part, and denied in part.

1. ACTION 1 and 8, CP 1; ACTION 1, CPs 2-4: Request for Moratorium

Your petitions (CPs 1-4) ask that FDA institute moratoriums on any non-medically necessary or elective eye surgeries other than for humanitarian purposes (CP 1, p. 31, CP 2, p. 25) and on the use of LASIK devices and devices used in PIOL implantation procedures (CP 3, p. 29, CP 4, p. 15). If FDA is not able to institute the moratoriums you describe, you request that the agency withdraw currently approved devices, so that they would no longer be available in interstate commerce or used in exempted investigational research (CP 1, p. 31 and 33; CP 2, p. 24; CP 3, p. 29). You contend the devices referenced in your petitions fail to meet the safety and effectiveness thresholds you identify, and that, therefore, their approvals should be withdrawn. Based on our review of the information you submitted, our understanding of the pre-clinical and clinical data provided to support the marketing of these devices, and our monitoring of the postmarket experience with these devices, the agency concludes that these actions are not warranted.

Additionally, you ask that FDA prohibit the use of certain approved devices by practitioners, although your petitions recognize that FDA does not have the authority to regulate the practice of medicine by which state-licensed professionals may use legally marketed devices in ways most beneficial to their individual patients. (CP 1, p. 4, CP 2, p. 3, CP 3, p. 7, CP 4, p. 6.) Notably, section 906 of the Federal Food, Drug, and Cosmetic Act (FDCA or the act) (21 U.S.C. § 396) provides that "[n]othing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." You contend, however, that evidence exists that certain licensed professionals have engaged in practices that fall outside the scope of this provision and that FDA is obligated

to impose applicable enforcement measures in accordance with the FDCA. In fact, FDA does not have authority to impose penalties against a state-licensed practitioner for violating state-imposed standards of patient care.

We, therefore, deny your request for the specified moratoriums, find no basis at this time for withdrawing the existing medical device approvals you discuss in your petitions, and have no authority to interfere in the practice of medicine by state-licensed professionals.

2. ACTION 2, CPs 1-4: Risk-Benefit Assessment Favors Moratorium

Each of your petitions suggests that the potential risks associated with the use of LASIK and PIOL devices outweigh their potential benefits, and that, therefore, the moratoriums or device approval withdrawals you request are necessary to ensure protection of the public health. (CP 1, p. 32, CP 2, p. 25, CP 3, p. 30, CP 4, p. 15). You further maintain that, because you believe other devices are now available that are safer than many of those approved previously, the agency should revoke its approval of those previously-approved devices, regardless of whether their manufacturers have met the applicable premarket requirements under the FDCA.

We disagree. Clinical studies assessing risk and benefit were performed to support the approval of each marketing application for the lasers (see also our response to Action 4) you identify in your petitions. The FDCA does not require manufacturers who have established that their products may be legally marketed through the 510(k) or PMA process to perform postmarket comparative studies of their devices with newer legally marketed products just because new products have become available on the market.

We have also reviewed the post market (after approval) experience with LASIK and have determined that the data do not support a withdrawal of the approval or clearance for any lasers or microkeratomes. In addition, there are on-going post-approval studies for both LASIK and PIOL devices, which we expect to yield additional safety and user information. Because these approved and cleared devices have been established to be reasonably safe and effective for their conditions of use, the agency has no basis to withdraw their approval or clearance. The agency believes that the postmarketing surveillance mechanisms currently in place appropriately safeguard the public health with regard to LASIK procedures and PIOL implantation.

Accordingly, we disagree that a risk-benefit analysis of the devices you discuss in your petitions favors the moratorium you request regarding devices used in LASIK and PIOL implantation procedures.

3. ACTION 3, CPs 1-4:
Hold An Advisory Committee Meeting

Each of your petitions request that FDA convene an advisory panel meeting to determine whether the data FDA reviewed when it cleared devices currently used in LASIK surgery and PIOL implantation continues to support their clearance (CP 1, p. 32, CP 2, p. 25, CP 3, p. 30, CP 4, p. 16). You also suggest that one or more members of the panel that originally reviewed the scientific data in support of LASIK and PIOL device approvals had conflicts of interest that should have prevented them from serving as committee members (CP 1, p. 20).

The agency disagrees that any member of the panel that reviewed LASIK and PIOL implantation, as referenced in your first petition, should have been prevented from serving on the panel. Regulations regarding members of FDA advisory committees are found at 21 CFR Part 14. Before allowing individuals to serve as panel members at any particular FDA panel meeting, the agency investigates their financial holdings, primary employment, consultant work, contracts/grants/cooperative research and development agreements (CRADAS), patents/royalties/trademarks, expert witness activities, as well as academic activities. Where applicable, members must execute a waiver affirming adherence to the ethical standards set forth by the regulations. (See, 21 CFR Part 14.80.)

The agency does agree, however, that continued panel discussions regarding postmarket experience with LASIK and PIOL implantation could complement the postmarket surveillance mechanisms that are currently in place. Accordingly, CDRH agrees to place these items on the agenda of the next scheduled open public hearing (OPH) of the Ophthalmic Devices Panel meeting. You may request an opportunity to present your concerns at this meeting. Upcoming panel meetings are announced at http://www.fda.gov/cdrh/panel/index.html. Instructions for "Providing a Request to Speak at an OPH" are attached for your information, and can also be found on the Internet at
http://www.fda.gov/oc/advisory/GuidancePolicyRegs/Guidance_OPH_FINAL_121704.html#IIA

Therefore, while we are denying your request to convene a special meeting of the panel, we are granting your request to have the panel consider quality of life and outcome issues associated with LASIK and PIOL devices at its next regular meeting as part of its agenda.

4. ACTION 4, CPs 1-4:
Total Product Life Cycle Review

Your petitions request that the agency "[o]versee the entire life cycle of these devices--from production through distribution, and consumption/use of these class I [sic] devices to assess whether the products are as safe as labeled and safe period [sic] as stipulated in their PMA

approvals." (CP 1, p. 32, CP 2, p. 26, CP 3, p. 31, CP 4, p. 16.) You correctly state that such oversight is consistent with the agency's mission to protect the public health. In fact, you identify several mechanisms by which the agency does already oversee the product lifecycle of all medical devices, including devices used in LASIK and PIOL implantation procedures.

Premarket product review is one way FDA ensures the safety and effectiveness of medical devices. Accordingly, FDA has approved or cleared LASIK and LASIK-related devices because the data considered in support of each PMA or 510(k) meet the statutory standard for approval or clearance. Under the FDCA and FDA's regulations, the agency approves a PMA when the data provide reasonable assurance that the device is safe and effective for its conditions of use (See, FDCA section 515 (d) or 21 CFR Part 814.). Under the FDCA and FDA's regulations, the agency clears a 510(k) when the data support the determination that the device is substantially equivalent to another legally marketed device (FFDCA section 513 (i)). At the time of the approval of both PIOLs, as a condition of approval, both sponsors were requested to conduct post-approval studies collecting five (5)-year follow-up data to evaluate vision-threatening adverse events associated with the use of PIOLs. These studies are currently ongoing.

The Quality System (QS) regulations found at 21 CFR Part 820 also ensure product safety. These regulations set forth current good manufacturing practice (CGMP), and are "intended to ensure that finished devices will be safe and effective and otherwise in compliance with the [FDCA]." (See 21 CFR § 820.2.) These regulations require that all medical device manufacturers establish and maintain quality production processes appropriate for the specific medical device(s) being designed or manufactured (see, 21 CFR §§ 820.5 and 820.20).

FDA also collects postmarket information on medical devices. One tool FDA uses is its Medical Device Reporting (MDR) regulation, which requires manufacturers, importers, and user facilities to notify FDA of adverse events associated with the use of medical devices. Similarly, FDA's MedWatch program allows consumers and healthcare providers to voluntarily report problems they believe are associated with the medical products they use. MedWatch can be reached by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail at MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or online at http://www.fda.gov/medwatch/report.htm. Additionally, the agency has implemented the Medical Product Safety Network (MedSun), a subset of FDA's MedWatch reporting program that currently consists of 350 health care facilities nationwide who voluntarily fulfill their mandatory reporting requirements through this Network. Finally, FDA is in the process of establishing SightNet , a reporting system designed to identify, understand, and solve information specific to problems with ophthalmic devices by way of an Internet-based reporting system, SightNet will operate as a sub-network within the MedSun system. However, the postmarket information found within our databases, regarding the devices mentioned in your petitions, does not suggest that, at this time, there are adverse events that are unanticipated or

occurring at an unexpected rate. Rather, these findings support the agency's current regulatory approach to the devices in your petitions.

We believe that the agency's ongoing efforts, from premarket review to postmarket surveillance, appropriately constitute the oversight of LASIK and PIOL devices requested in each of your petitions. Because FDA will continue these efforts, your request that the agency oversee these products throughout their lifecycle is granted.

5. ACTION 5, CPs 1-4:
Conduct Comprehensive Study of Injuries and Risks

Each of your petitions requests that FDA "[c]onduct a retrospective comprehensive study of the incidence and prevalence of injuries to track ALL the relevant risks [associated with the referenced devices]" and that FDA "[g]ather and collect all surveillance and monitoring data to allow proper education and targeting of interventions." (CP 1, p. 33 , CP 2, p. 26, CP 3, p. 31, CP 4, p. 16). As previously discussed under Action 2, clinical studies to assess risk and benefit were performed to support the approval of each marketing application of LASIK lasers and PIOLs. These were prospective clinical trials in which the prevalence and incidence of adverse events were collected. All were evaluated by the FDA, and in some cases, by the panel. Through various media, from device and patient booklets to our own LASIK and PIOL websites (http://www.fda.gov/cdrh/lasik/ and http://www.fda.gov/cdrh/phakic/), the FDA informed the public about these data. In Action 4, we described some of the surveillance mechanisms that are in place for FDA to monitor the postmarket experience with these devices.

The agency has no basis at this time to order manufacturers of devices used in LASIK procedures, that are not currently conducting post-approval studies, to conduct postmarket surveillance studies of their devices. Both PIOLs currently approved for use in the United States are undergoing post-approval study. Outcomes from these studies will be utilized in updating FDA's PIOL website.

Therefore, while FDA is not able to conduct the comprehensive retrospective study described in your petitions, prospective studies of injuries and risks associated with devices used in LASIK and PIOL implantation were performed and are being conducted. Additionally, FDA, in collaboration with other HHS agencies and professional organizations, is planning to conduct a prospective study assessing quality of life (QOL) issues secondary to LASIK. Your request to track the incidence and prevalence of risks and injuries associated with LASIK and PIOL devices is, therefore, granted.

6. ACTION 6, CPs 1-4:
Phase-Out Older Devices
As Newer Technology Becomes Available

Your petitions request that "[i]f newer devices become available which have better safety records, then remove the approvals for the older devices." (CP1, p. 33, CP2, p. 26, CP3, p. 31, CP4, p. 16) As an example, you contend that "[i]ntralase lasers have been shown to have a much better safety record (as much as 10 times fewer problems and less serious problems) than mechanical microkeratome blades for making LASIK flaps." (CP1, p. 26; CP2, p. 33; CP3, p. 31; CP4, p. 16.) However, the agency notes that laser keratomes and mechanical keratomes have different safety issues and a different user base, and that the safe use of these device types, particularly the mechanical keratome, is strongly correlated to the experience of the user. Nonetheless, obsolete devices are often phased out of the marketplace when replaced by new technology, when product design changes are made, or consumer use decreases. The agency has no authority to rescind statutorily approved devices simply because new products have been cleared for marketing.

Your request that FDA remove or rescind existing product approvals as new medical device products become available is, therefore, denied.

7. ACTION 7, CPs 1-4:
Develop A National Agenda for the
Prevention of Elective Refractive Eye Surgery

Each of your petitions requests that FDA "[d]evelop a national agenda for the prevention of injuries from elective refractive eye surgery and implement it through coordination of federal efforts across a variety of private and public agencies including the Department of Health and Human Services." (CP 1, p. 33, CP 2, p. 26, CP 3, p. 31, CP 4, p. 16.) You state further that "[u]niform legislation should be required by law, enacted and enforced in every state to mandate specific minimal safety practices." (CP 1, p. 33, CP 2, p. 26, CP 3, p. 32, CP 4, p. 16.) You discuss the potential benefits from standardized testing and urge greater oversight regarding investigational and post market studies.

FDA has implemented a plan for informing prospective patients of the risks and benefits of an elective refractive eye surgery. One part of the plan is that all LASIK devices and PIOLs are required to come with patient labeling. Another cornerstone of this plan are websites that serve as informational clearinghouses with answers to frequently asked questions about laser eye surgery and PIOLS. These websites can be found at http://www.fda.gov/cdrh/LASIK/ and http://www.fda.gov/cdrh/phakic/. These websites are continuously updated as new information (e.g., new device approvals) becomes available, or to address recurring questions. You may send

comments and suggestions for updates by using the "Contact Us" page on the LASIK web site, or you may send a message directly to: LASIK@CDRH.FDA.GOV. A more detailed discussion of updates that are already underway is found under Action 11.

FDA also has a Memorandum of Understanding with the Federal Trade Commission (FTC) on the promotion and advertising of FDA-regulated products and has collaborated with FTC in outreach activities regarding LASIK devices. Together, the agencies try to ensure that manufacturers do not send consumers misleading messages on the safety and effectiveness of FDA-regulated products, including medical devices used in LASIK.

FDA believes that the mechanisms the agency has implemented to protect the public health regarding LASIK and PIOL medical devices address, and will continue to address, the health risks associated with these procedures. The agency will certainly consider further actions if future assessments by FDA of postmarket data indicates the need for additional measures.

8. ACTION 8, CPs 3 and 4:
Conduct An Independent Investigation of FDA

Your two most recent petitions (CPs 3 and 4) request "an independent investigation of the Government including specifically the FDA." (CP3, p. 32, CP4, p. 17) You suggest that the "investigations could be conducted by the Office of the Inspector General, the Department of Justice, Congress, the Senate, Office of the Attorney General . . . [and that the] purpose of the investigation could be to correct the problems pointed out in this petition and/or evaluate pressing charges against advisors or employees of the FDA or government officials involved in any criminal activity including, but not limited to racketeering or breach of Federal laws." (CP 3, p. 32 & CP 4, p. 17.)

FDA believes the ethical conduct of its employees is of critical importance and the agency would undertake appropriate action if there were evidence that its employees were potentially engaged in criminal activity. We do not believe the non-specific information in your petitions provides a basis for further investigation. However, you may certainly contact whichever government agencies you believe appropriate to request the other actions you desire. We are, therefore, denying your request to conduct an independent investigation of FDA.

9. ACTION 9, CPs 3 and 4:
Determine Whether Premarket Approval is Appropriate for Microkeratome Devices

Your two most recent petitions (CPs 3 and 4) request that FDA review "whether or Not [sic] a 510K approval [sic] is even appropriate for a dangerous medical device [microkeratome devices] that can and does cause serious injury including blindness . . . [because the] Petitioner believes only a PMA is a sufficient degree of approval. In addition if warranted and appropriate, the petitioner requests multiple investigations and seeks to press criminal charges." (CP 3, p. 33; CP 4, p. 18.)

As discussed previously in Actions 2 and 5 above, the agency has reviewed the devices you discuss within the existing statutory framework for classifying medical devices and believes it has classified these devices appropriately. This existing statutory framework not only provides for product review by expert panels, but it also requires that the agency give notice of rulemaking so that public input is included in the process. These processes have been followed with respect to microkeratomes, as they are for all devices FDA regulates.

Further, with specific regard to mechanical ophthalmic microkeratomes, these devices have been available for more than 20 years and have always been intended for cutting the cornea. Our review of the MDR database has not shown increased adverse event reports associated with these devices. In addition, FDA recently issued guidance on keratomes, http://www.fda.gov/cdrh/ode/guidance/1604.html, to help manufacturers prepare appropriate premarket study design and testing, and will give the user additional information on the safe and effective use of the device. Finally, and as is true of most surgical medical instruments, surgeon training, skill, and experience are also very important for the safe use of the device.

Accordingly, your request to regulate microkeratomes as class III devices requiring premarket approval is denied.

10. ACTION 10, CPs 3 and 4:
Launch An Investigation

Your two most recent petitions (CPs 3 and 4) request that FDA conduct an investigation "of any and ALL users of these regulated medical devices (e.g., Doctors) suspected of violating the FDA labeling and/or using these devices in any type of adulterated manner (including evaluating criminal charges) OR off-label use without patient benefit or without informed patient consent (which is also an adulterated use of a regulated medical device)." (CP3, p. 33; CP4, p.

18.) You emphasize that you believe that not all patients are provided informed consent for the reported off-label use of LASIK devices.

As discussed previously in this letter, the FDCA contains no basis for an enforcement action by FDA concerning the conduct of a state-licensed eye care practitioner because of the way that practitioner uses or prescribes legally marketed devices as part of his or her care for individual patients. To reiterate, medical professionals are regulated by the state authorities where they practice, and legal remedies exist at the state level if you believe a cause of action exists.

We must, therefore, deny your request that FDA launch an investigation of any and all doctors you suspect of violating LASIK product labeling requirements by prescribing an off-label use for these products.

11. ACTION 11, CP 3; ACTION 12, CP 4:
Work With Petitioner to Protect the Public Health

Your two most recent petitions request that FDA "[w]ork with the petitioner, medical Doctors, and/or others to come up with other ways to adequately protect the public health." (CP3, p. 33, CP4, p. 18.) FDA agrees that working with the public is important in ensuring the public health. One way that FDA promotes public health is by providing risk and benefit information to prospective patients about elective refractive eye surgery. As discussed previously, all LASIK devices and PIOLs come with patient labeling that identifies the risks and benefits of the devices. Additionally, FDA has established a website that serves as an informational resource to patients and consumers considering LASIK. Again, this website can be found at http://www.fda.gov/cdrh/LASIK/ .

On June 12th, 2007 FDA updated its LASIK website to include additional information regarding the single-use requirement for microkeratome blades. The website is also being updated to include an animated video that more clearly explains LASIK procedures. Similar to the agency's LASIK website, CDRH has implemented a PIOL website (http://www.fda.gov/cdrh/phakic/) to provide risk and benefit information to consumers considering PIOL .

FDA will continue to update and revise these resources as appropriate in response to new information and public comments the agency receives. The agency believes it has, therefore, granted your request to work together to protect the public health.

12. ACTION 11, CP 4:
Combining Enforcement Efforts
With State and Local Governments

Your most recent petition (CP 4) states that FDA "should work with State and Local authorities to enforce medical Doctors DUTY TO WARN." (CP 2, p. 18) You further contend that "[d]octors knowingly injur[ed] patients and [did] nothing to notify the proper authorities about the injuries including the FDA." (CP 4, p.18) Finally, you state that FDA "should provide a penalty consistent with the severity and type of injuries that have occurred multiplied by the number of patients injured" (CP 4, p. 18).

The agency does work with state and local Governments to enforce provisions of the FDCA. However, with regard to your request that FDA work with these agencies and mandate the warnings about medical practice your petitions request, the act does not provide for such authority. In addition, the agency is not aware of the reporting violations your petition discusses with regard to injured patients. Again, however, state licensed doctors engaged in an established doctor-patient relationship may legally prescribe the off-label use of a legally marketed device. As previously discussed, nothing in the act permits the agency to impose a penalty against a state-licensed practitioner for doing so.

13. CP2:
Enforcing the Single Use Requirement
for Microkeratome Blades

With regard to your second citizen petition, you specifically address the single-use requirement for microkeratome blades. You state that "when used in LASIK surgery, every patient MUST receive new microkeratome components (e.g., blades and cannulas), regardless of whether the device is operated by a physician, or a technician working under the supervision of a physician." FDA agrees. In fact, this information regarding microkeratome components is required in the devices' labeling. FDA has recently updated the agency's LASIK website to reflect this language.

You additionally state that "[r]euse also appears to be an off-label use or even violation of the FDA approval." (CP 2, pp. 4, 11, and 12.) Again, the agency agrees. It is important to note, however, that the FDCA defines "single-use device" as "a device that is intended for one use, or on a single patient during a single procedure." (See, 21 U.S.C. 321(ll)(1).)

With regard to the off-label use of these products by physicians, the FDA is not empowered to take action. As discussed previously, FDA does not have the authority to regulate the practice of medicine. (See 21 U.S.C. § 396.) Thus, the agency is unable to grant your request to enforce the single-use requirement for microkeratome blades on the physicians who use the blades. However, the website is being updated to emphasize that microkeratomes are single-use devices.

Conclusion

If you have any questions in this regard, please contact Ms. Domini Cassis by e-mail at domini.cassis@fda.hhs.gov, or by telephone at 240-276-2342.

Sincerely,

Linda S. Kahan

Linda S. Kahan
Deputy Director
Center for Devices
and Radiological Health

Enclosure:

The Open Public Hearing
FDA Advisory Committee Meetings

Guidance

The Open Public Hearing FDA Advisory Committee Meetings

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DRAFT GUIDANCE
[PDF Version of Guidance]

This guidance is being distributed for comment purposes only.

Comments and suggestions may be submitted at anytime for agency consideration to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that is published in the *Federal Register*. [Federal Register Notice Announcing Availability of Guidance]

For questions regarding this document, contact the Advisory Committee Oversight and Management Staff
301-827-1220

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner

Additional copies are available from:

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[1]Guidance

The Open Public Hearing FDA Advisory Committee Meetings[2]

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create nor confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

The Food and Drug Administration (FDA) encourages participation from all public stakeholders in its decision-making processes. Every advisory committee meeting includes an open public hearing (OPH) session, during which interested persons may present relevant information or views orally or in writing. 21 CFR § 14.25(a). FDA's regulation, 21 CFR § 14.29, requires that a minimum of 60 minutes per meeting be dedicated to an open public hearing session for oral presentations, unless public participation does not last that long. For meetings that extend more than 1 day and/or meetings with multiple topics, the OPH session can be divided into multiple parts. If there is an overwhelming interest by the advisory committee in a specific topic, then the committee chair[3] may extend the OPH session.

The time and location of the meeting and the OPH session is published in the *Federal Register* (21 CFR § 14.20) at least 15 days before a meeting.

This guidance is intended to answer questions about how the public may participate at an open public hearing session. This includes, but is not limited to, general members of the public; individuals or spokespersons from the regulated industry (except the sponsor whose product is under review); consumer advocacy groups; or professional organizations, societies or associations.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. ORAL PARTICIPATION IN AN FDA ADVISORY COMMITTEE OPEN PUBLIC HEARING

A. Providing a Request to Speak at the OPH:

An interested person who wishes to be assured of the right to make an oral presentation at an advisory committee meeting shall inform FDA orally or in writing before the meeting. 21 CFR § 14.29(b). The interested person shall submit the request to the FDA contact person designated in the *Federal Register* (FR) notice by the listed deadline date. 21 CFR § 14.29 (b). FDA staff makes every effort to accommodate a speaker's request. FDA recommends that the request be submitted by mail, telephone, facsimile, or e-mail. Participation is handled on a first come-first serve basis through the request process.

The interested person should include the following with the request:

- Name of the individual or;
- Name of the group, including, the name of the spokesperson making the presentation, a description of the constituency that the group represents, and a brief mission statement of the group;
- Contact information (mailing address, e-mail address, telephone and fax numbers);

The interested person shall also include the following in the submission:

- A description of the general nature of the presentation, pursuant to 21 CFR § 14.29 (b). The submitter can include an outline of the presentation to satisfy this requirement. Whenever possible, all written information to be discussed by that person at the meeting should be furnished in advance to FDA, pursuant to 21 CFR § 14.29(b)(1); See subsection D below.
- Amount of time requested for the presentation, pursuant to 21 CFR § 14.29(b). The allotment time is dependant upon the number of requests. FDA usually allots 5 to 10 minutes per person. However, if a large number of speakers have requested to address the committee, FDA may reduce the time allotment for each speaker pursuant to 21 CFR § 14.29(b)(2) and/or extend the time of the OPH session. In the interest of obtaining as many points of view as possible, FDA may require speakers with similar statements to consolidate their presentations into a single presentation, pursuant to 21 CFR § 14.29(b)(2). In the interest of fairness, all speakers are asked to adhere to their allotted time.

Audio-visual/media equipment is available at advisory committee meetings. FDA asks that the interested person provide a written request for use of the equipment along with an electronic version of the presentation or any overheads at least one week in advance of the meeting. Please consult with the FDA executive secretary (FDA staff)[4] on issues related to the compatibility of software/hardware for your presentation.

B. Confirmation to Speak at the OPH

1. FDA staff intends to contact speakers by e-mail, facsimile, or telephone to

confirm their participation.

2. FDA intends to assign a time allocation. In the event of scheduling changes and if time permits, FDA staff will contact the speaker concerning these changes

3. If the speaker is delayed or is unable to attend the meeting, FDA recommends that an FDA representative be contacted. If the speaker would still like to make a presentation and time and resources permit, it may be possible to arrange for an alternative time to speak during the meeting; to have the speaker's statement read by a speaker representative; or to have the statement, or a summary of the speaker's statement, made part of the public record via the public docket. However, once the public hearing portion of the meeting has ended, further oral comments from the public will only be accepted at the discretion of the FDA advisory committee chair.

C. Confirmed Speaker Check-In the Day of the Meeting

1. Check-in is at the registration table. Speakers should introduce themselves to the Executive Secretary and other FDA staff. OPH speakers often have a designated seating area.

2. Please work with the Executive Secretary or other designated FDA staff to facilitate your presentation (e.g., slides) and handout distribution.

D. Handouts for the Day of the Meeting

1. FDA distributes to the advisory committee before or at the meeting those copies of handouts received from public speakers prior to the deadline in the FR notice, pursuant to 21 CFR § 14.29(b)(1).[5]

2. A copy of slide presentations should be given to FDA for posting on the FDA web site at http://www.fda.gov/oc/advisory/default.htm.

3. A copy of the written information will be included in the permanent record of the meeting. 21 CFR § 14.60(b)(3).

E. Logistics of an Oral Presentation

1. A podium or lapel microphone is available or, alternatively, an audience microphone is located conveniently on the floor.

2. A timer is used to monitor the speaker. If the timer is not used at a particular meeting, the Committee Chair or the Executive Secretary signals the speaker when his or her allotted time has expired.

3. When the oral presentation concludes, FDA recommends that the speaker remain at the podium in case there are questions from the FDA advisory committee.

4. All oral statements are recorded in the transcript of the meeting. Meeting transcripts are posted on the FDA web site approximately three to four weeks after the meeting takes place.

III. FINANCIAL DISCLOSURE

The law requires that the Food and Drug Administration's scientific advisors, who are usually special Government employees (SGEs), disclose potential financial interests or relationships that they may have with the sponsor and/or competitors of the product under discussion at an advisory committee meeting. The financial interests requiring disclosure include stock, grants, consulting, teaching, speaking and writing engagements, expert testimony, patents, and royalties. In addition, the financial interests of a spouse, minor child, and employer are imputed to the committee member.

As noted in this Guidance, at every advisory committee meeting, at least one hour is set aside for an open public hearing. At this time, speakers from the general public may make a presentation to the advisory committee. Advisory committee meetings consist of either particular or general matters for discussion and consideration. Particular matters before an advisory committee relate to a specific regulated product and affect a specific manufacturer and its competing products/manufacturers (e.g., NDA, PMA, PLA/BLA, efficacy supplement for new indication). General matters before an advisory committee do not relate to a specific regulated product but instead relate to scientific findings or regulatory issues that may affect various members of the public and regulated industry.

At the commencement of each OPH session, the Chair of the particular advisory committee meeting reads one of the following statements, addressing the issue of financial disclosure for all open public hearing speakers.

A. Instructive Statement for Particular Matters Meetings

Both the Food and Drug Administration (FDA) and the public believe in a transparent process for information gathering and decision-making. To ensure such transparency at the open public hearing session of the advisory committee meeting, FDA believes that it is important to understand the context of an individual's presentation. For this reason, FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement, to advise the committee of any financial relationship that you may have with the sponsor, its product, and if known, its direct competitors. For example, this financial information may include the sponsor's payment of your travel, lodging, or other expenses in connection with your attendance at the meeting. Likewise, FDA encourages you at the beginning of your statement to advise the committee if you do not have any such financial relationships. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

B. Instructive Statement for General Matters Meetings

Both the Food and Drug Administration (FDA) and the public believe in a transparent process for information gathering and decision-making. To ensure such transparency at the open public hearing session of the advisory committee meeting, FDA believes that it is important to understand the context of an individual's presentation. For this reason, FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement, to advise the committee of any financial relationship that you may have with any company or group that may be affected by the topic of this meeting. For example, the financial information may include a company's or a group's payment of your travel, lodging, or other expenses in connection with your attendance at the meeting. Likewise, FDA encourages you at the beginning of your statement to advise the committee if you do not have any such financial relationships. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

After each presentation, the Chair or a committee member may question the person concerning the scientific content of his or her presentation. However, neither the Chair nor any committee member should further question the person regarding any potential financial relationships. If the open public hearing participant's statement contains no information about his or her financial relationships relative to the meeting topic, FDA intends to assume

that the participant has made a conscious decision not to disclose this information.

IV. REFERENCES

A. FDA Advisory Committee Home Page – http://www.fda.gov/oc/advisory/default.htm
B. FDA Advisory Committee Annual Calendar of Meetings (Most current calendar year link can be found on the FDA Advisory Committee Home Page)
C. FDA Advisory Committee Information Line Code Numbers – http://www.fda.gov/oc/advisory/acphonecodes.html
D. CODE OF FEDERAL REGULATIONS (CFR PART 14) – http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=14.84

FOOTNOTES:

[1]This guidance has been prepared by the Advisory Committee Oversight and Management Staff, Office of External Relations, Office of the Commissioner, Food and Drug Administration.

[2]This guidance applies to all FDA advisory committees including the panels of the Medical Devices Advisory Committee.

[3]The chair is an experienced committee member appointed to preside at committee meetings and ensure that all rules of order and conduct are maintained during each session. 21 § 14.30.

[4]The Executive Secretary is the Designated Federal Official (DFO) who coordinates the activities of the advisory committee, serves as the link between committee members, FDA, industry and the public.

[5]FDA plans to issue draft guidance in the future to address the issue of written material submitted after the deadline stated in the *Federal Register* notice.

[PDF Version of Guidance]
[Federal Register Notice Announcing Availability of Guidance]
