OCT 26 2016

Morris Waxler, PhD
President
Waxler Regulatory Consultancy LLC
1920 Arlington Place
Madison, WI 53726-4002

Re: Petition for Reconsideration [Docket Number FDA-2011-P-0022/PRC]

Dear Dr. Waxler:

This letter responds to your petition for reconsideration received on July 31, 2014 (Reconsideration Petition). The Reconsideration Petition requests that the Food and Drug Administration (FDA or the Agency) reconsider its June 23, 2014 response (Citizen Petition Response) denying your citizen petition filed on January 7, 2011 (Citizen Petition). The Citizen Petition requested that the Commissioner of Food and Drugs: (1) withdraw premarket approval for all laser-assisted in situ keratomileusis (LASIK) excimer lasers, and (2) issue a Public Health Advisory with a voluntary recall of these LASIK devices.

In the Reconsideration Petition, you argue that the Agency "did not adequately consider the public record of industry pressure on the Agency, the MEDWATCH reports, other sources of adverse event data, and conflation of patient satisfaction information with adverse event data." You request that the Agency reconsider the decision to deny the Citizen Petition.

FDA has considered the information submitted in the Reconsideration Petition, as well as the comments on it received by the Agency.[1] For the reasons described below, the Reconsideration Petition is denied.

I. BACKGROUND

The Citizen Petition requested that FDA withdraw premarket approval for and issue a Public Health Advisory regarding LASIK excimer lasers, arguing that the device applicants withheld and distorted safety and effectiveness data in their submissions to FDA and that LASIK creates "sick corneas." The Citizen Petition cited data from several approved premarket approval (PMA) applications, as well as published scientific literature, and also included your own analyses of the data.

[1] The discussion below, which expressly responds to issues raised in the Reconsideration Petition, also addresses the relevant comments (see 21 CFR 10.33(d)) submitted to the docket, which expressed support for arguments made in the Reconsideration Petition.

In the Agency's Citizen Petition Response, FDA described why the information in its totality did not satisfy the statutory requirements for withdrawal of the approved PMAs for LASIK excimer lasers or warrant the issuance of a Public Health Advisory with a voluntary recall of the devices. Specifically, after reviewing information included in the Citizen Petition, the published literature cited in the Citizen Petition, and other relevant information and data available to the Agency (see Citizen Petition Response at p. 7), FDA concluded that the following statutory requirements for PMA withdrawal had not been met: [2]

- the device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling (section 515(e)(1)(A) of the FD&C Act);
- on the basis of new information, evaluated together with the evidence available when the application was approved, there is a lack of showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling (section 515(e)(1)(B) of the FD&C Act);
- the application contained or was accompanied by an untrue statement of a material fact (section 515(e)(1)(C) of the FD&C Act); and
- on the basis of new information, evaluated together with the evidence before the Agency when the application was approved, the labeling of the device, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact (section 515(e)(1)(F) of the FD&C Act).

Regarding the request for a Public Health Advisory with a voluntary recall of the devices, the Agency stated that it did not believe such actions were warranted where: (1) FDA had not found any new safety concerns associated with the devices, (2) the risks associated with the devices were described in the patient labeling, and (3) FDA's website provided information about the devices and the procedures, including a summary of the most common risks and links to the Summary of Safety and Effectiveness Data and patient labeling for each approved device.

In the Citizen Petition Response, the Agency addressed your arguments that PMA applicants withheld and distorted safety data in their submission to FDA, and also noted that such allegations were not supported by any information provided in the Citizen Petition (see Citizen Petition Response at pp. 2 – 4). In addition, FDA responded to your claim that LASIK creates "sick" corneas (see Citizen Petition Response at pp. 4-7). Finally, FDA provided a list of actions that it has taken during its monitoring of postmarket data related to LASIK devices and promotional claims made about those devices (see Citizen Petition Response at pp. 7-8).

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[2] In the Citizen Petition Response, FDA noted that the Citizen Petition did not make any claims or provide information regarding the other withdrawal standards set forth in section 515(e)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act); this finding is not disputed in the Reconsideration Petition.

II. DISCUSSION

The Commissioner may grant a petition for reconsideration if the Commissioner determines the petition to be in the public interest and in the interest of justice (21 CFR 10.33(d)). Section 10.33(d) provides that the Commissioner shall grant a petition for reconsideration if the Commissioner determines that all of the following apply:

(1) The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered.
(2) The petitioner's position is not frivolous and is being pursued in good faith.
(3) The petitioner has demonstrated sound public policy grounds supporting reconsideration.
(4) Reconsideration is not outweighed by public health or other public interests.

A petition for reconsideration may not be based on information and views not contained in the administrative record on which the decision was made (21 CFR 10.33(e)).

We have reviewed the information submitted in the Reconsideration Petition. Contrary to the statements you make, we have determined that the Citizen Petition Response comprehensively and adequately addressed the relevant issues raised. The Reconsideration Petition asserts that FDA did not adequately consider the record of prolonged industry pressure on the Agency or use the correct data to evaluate the risks of LASIK devices. We disagree with these assertions.

FDA fully addressed these issues in Section II.A of the Citizen Petition Response (see Citizen Petition Response at pp. 2-4). See, for example, the following statements in the Citizen Petition Response:

- "We acknowledge that the visual symptoms you mentioned may occur following LASIK surgery but FDA was not 'pressured' to classify these as symptoms. Not all of these visual symptoms are clinically significant enough to warrant classification as an adverse event (for example, because they are reported as being mild)."
- "[T]he full spectrum and persistence of all post-LASIK visual symptoms observed in the clinical studies submitted in the PMA application were considered in FDA's evaluation of the overall benefit-risk profile of each LASIK device during the premarket review process."
- "Although it is important for consumers to understand the potential risks associated with LASIK devices, FDA does not believe the information contained in your petition changes the overall benefit-risk profile of approved LASIK devices."

It appears that you merely disagree with the conclusions that the Agency reached upon considering the information, which is not a basis for FDA to grant a reconsideration petition (see 21 CFR 10.33(d)).

As such, we have determined that relevant information and views contained in the administrative record were adequately considered by FDA (see 21 CFR 10.33(d)(1)); we need not address whether the other criteria in 21 CFR 10.33(d) have been met. The granting of the

Reconsideration Petition would, therefore, not be "in the public interest and in the interest of justice" (21 CFR 10.33(d)). For these reasons, we are denying the request for reconsideration.

III. CONCLUSION

For the reasons described above, the Agency denies the Reconsideration Petition.

Sincerely yours,

Leslie Kux
Associate Commissioner for Policy