FDA Ruling Update – Tear Duct Occluder Labeling

4/27/2017

Subject: DEN140022 - Inquiry regarding labeling change
From: "Fedorko, Daniel (FDA)" <Daniel.Fedorko@fda.hhs.gov>
Date: Thu, April 27, 2017 3:22 pm
To: "stephen.chen@innovatex-inc.com" <stephen.chen@innovatex-inc.com>
Cc: "Bancos, Simona" <Simona.Bancos@fda.hhs.gov>,
"DEN140022@docs.fda.gov" <DEN140022@docs.fda.gov>

Hello Mr. Chen,

You have requested a change in the prescription use only statement [CFR 21 Part 801.109(b)(1)] for the Tear Duct Occluder granted under de novo DEN14022. Currently, the labeling for the Tear Duct Occluder states "Federal law restricts this device to sale by or on the order of an ophthalmologist." You propose to change the labeling to state that "Federal law restricts this device to sale by or on the order of an ophthalmologist or optometrist." While the proposed change seems reasonable, we believe that it would be more adequate to include in the labeling "Federal law restricts this device to sale by or on the order of a licensed eye care professional." We do not believe that this change requires a 510(k) submission. Please be advised that you should keep internal documentation of any changes made to the labeling for your device. For further details, please refer to the guidance document "Deciding when to submit a 510(k) for a change to an existing device" available at: https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm514771.pdf

Kind Regards.

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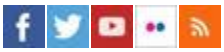

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