justifies an omission in accordance with 21 C.F.R. 814.20(d), a PMA shall include a complete description of "[t]he methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with current good manufacturing practice can make a knowledgeable judgment about the quality control used in the manufacture of the device."

You are responsible for providing all manufacturing information required under the FD&C Act and under FDA's regulations. In order to do so, you should consider in detail each section of FDA's Quality System Regulation, found at 21 C.F.R. Part 820 (reprinted in the Appendix to the Medical Devices Quality Systems Manual located at FDA's website, www.fda.gov/cdrh/dsma/cgmphome.html). If you decide not to manufacture additional units of your device and believe that specific types of manufacturing information are not applicable for your device as a result of this decision, you will be required to identify the omitted information and
justify the omission, in accordance with 21 C.F.R. 814.20(d).

If you have any questions about this letter please call Mary Lou Davis at (301) 594-4613.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health