



February 9, 2018

Ms. Shirley S. Xu  
Materials Safety Licensing Branch  
Division of Material Safety, State, Tribal, and Rulemaking Programs  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

**Re: License No. 32-31005-01E**

**Docket No. 030-37764**

Dear Ms. Xu,

This letter is in response to your correspondence dated January 10, 2018 requesting additional information pertaining to the Sterigenics amendment request initially filed on November 16, 2017. The amendment request seeks a name change on License 32-31005-01E.

Per your January 10, 2018 correspondence, the additional items and /or clarifications are listed as follows:

1. Please provide a copy of your radioactive material possession and use license issued by the State of North Carolina reflecting the name change of your company. ***The corporate rebranding effort resulted only in a change to the name of the companies identified in Sotera Health's November 16, 2017 letter. The Sotera Health subsidiary which holds the North Carolina radioactive materials licenses, Sterigenics U.S., LLC, was not affected by the corporate rebranding. Accordingly, Sotera Health has not sought an amendment to change the licensee name on the North Carolina licenses.***
2. Please confirm that no changes were made to the product since the last amendment. ***On behalf of Sotera Health, I confirm that there have been no changes to the product since the last amendment.***
3. Provide the new label for the device indicating the new company name and the effective date of the label change. ***This item is non-applicable as the "device" is an irradiated gemstone.***
4. Confirm that the Quality Assurance Program will remain the same for Sotera Health LLC. ***The current QA Program associated with the license is relevant to the shipment of irradiated gemstones. Therefore, the QA Program will remain the same for Sotera Health LLC.***



If you have any questions or comments, please contact me at 630.928.1758 or at [khoffman@sterigenics.com](mailto:khoffman@sterigenics.com).

Sincerely,

*KA Hoffman*

**Kathleen Hoffman**  
Sr. Vice President — Sterigenics Global Environmental, Health & Safety and Technical Services  
Sotera Health LLC

cc: A. Polonsky, Morgan Lewis & Bockius, LLP  
M. Klaben, General Counsel, Sotera Health LLC