



IMPROVING QUALITY WITH SCIENCE

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To Our Medical Device Customers:

This letter is to clarify the status of our FDA registration for medical device sterilization and FDA requirements relating to shipment of sterilized medical devices. FTSI has maintained continuous registration as a contract sterilizer since 2001 as facility number 1054811. In 2005, FDA revised 21 CFR 807.20 so that registration was no longer provided for contract sterilizers who "Sterilize devices on a contract basis for other registered facilities who commercially distribute the devices."

However, FDA defines commercial distribution on the part of contract sterilizers as shipping of customer-owned medical devices from the sterilization facility to a third party. In plain terms, if your medical device is received at our facility, sterilized and then trans-shipped to your customer, then FTSI is engaged in commercial distribution of your product. FTSI is committed to customer service and will continue to facilitate trans-shipments of our customer's sterilized products to third-parties. If your shipping requirements indicate that your sterilized product is not being returned to your facility, FTSI will prepare and submit FDA form 2892 which informs FDA that we are engaged in the distribution of your product. This is a one-time action that is not required on subsequent trans-shipments of items having the same product code. This process will be seamless to you and no action is required on your part.

Please contact Susan LeFrancois if you have questions or desire more information relating to these FDA requirements.

Sincerely,

Susan LeFrancois, Ph.D.
Director of Regulatory Affairs
and Quality Assurance
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