



Dear Valued Customer,

May 18, 2026

BioSpectra shall notify all active customers of any material changes to our GMP products or manufacturing processes of GMP products by providing written notice at least six (6) months prior to the date the change will take effect, unless the change is considered an emergency. Any emergency Change Control Notice shall be delivered to the Customer as soon as it is commercially feasible. Customers are considered “active” if they have purchased a product within the last twenty-four (24) months.

Change Control notifications shall be required for any change that may affect the purity, identity, stability, labeling, appearance, or function of any GMP product. Such changes may result from, but are not limited to a change in:

- Manufacturing Process
- Product Specifications
- Raw Material
- Components
- Manufacturing Location
- Part Numbers
- Packaging Configuration
- Labeling
- Discontinuation of Product
- Ownership and/or Company Name
- Change in test methods (if not compendial)

BioSpectra’s Customer Service team will issue relevant change notifications to all active customers. If an end user purchases a GMP product through a distribution channel, BioSpectra will send the notification to the distributor. If the end user would like to request BioSpectra send a notification directly to them as well, either the end user or the distributor can request via email BioSpectra’s customer service at customer.service@biospectra.us. BioSpectra’s Customer Service team maintains an additional contact list for end users to ensure all parties receive the notifications as requested. Any additional requirements related to change notifications can be addressed in a Quality Agreement with BioSpectra.

Respectfully submitted,

Connie Augustine
Director of Commercial Operations
100 Majestic Way | Bangor, PA 18013
connie.augustine@biospectra.us
+1.610.599.3428