charles river

14 September 2020 CN # 20-003

Dear Valued Customer,

Charles River strives to provide the highest level of support to our global customers by delivering industry-leading scientific and technological advances. As part of our ongoing effort to better serve our customers, this is an advance notification that the product in **Table 1: End-of-Life Product** will no longer be available through Charles River as of the date listed in the table. We will be offering support through expiration for this product following the discontinuation.

Table 1: End-of-Life Product

PRODUCT CODE	PRODUCT DESCRIPTION	AVAILABLE THROUGH:
BG120	Endotoxin-Specific Buffer	October 2020

This notification is intended to provide further details regarding this discontinuation. Any product that is purchased by Charles River from WAKO Japan/FujiFilm prior to this date will continue to be sold through at least October 31st, 2020 or until inventory of the remaining lots has been depleted or expires.

While the above product will be discontinued from our portfolio, Charles River is confident in the recommended available alternative, and our teams are prepared to assist in the transition. The following provides information on the product that will be available and will serve as an alternative to the product being discontinued.

- Replacement for product code BG120 – Endotoxin-Specific Buffer:
    - Endotoxin-Specific Buffer, (Product Code BG200) is Charles River's own internally manufactured buffer and will be launched in October 2020. This buffer is being manufactured for distribution with the current processes once launched. The Charles River buffer is functionally the same; however, its new product code BG200, and labeling will differentiate it from the BG120. Similar to the Wako Japan/FujiFilm Endotoxin Specific Buffer, our buffer has been formulated to block beta glucans from interfering with endotoxin results.

The labeling and Certificate of Quality (CoQ) will reflect the appropriate changes, and it is important that you update any incoming specifications accordingly. A copy of the new vial and box label are attached to this correspondence in Attachment 1: BG200 Labels, and a copy of the CoQ is attached to this correspondence in Attachment 2: BG200 Certificate of Quality, as well.

Side-by-side comparisons have been performed to ensure equivalency with respect to BG200's intended use. A summary of the results is provided in Attachment 3: BG120 & BG200 Comparison Study Results. All study related records will be available for review via an onsite audit. We have determined that this change does not represent a change in the experimental test conditions that would adversely affect test results as described in the USP and EP. Should you decide to confirm our study results, both BG120 and BG200 products will be available for your suitability studies. Please contact Endosafe-Support@crl.com if you require advance vials of BG200.

There are many factors that contribute to our overall decision-making process regarding updates, including rapid advancements in technology, the constantly evolving standards of care and maintenance, and specific mandates regarding regulatory compliance. We continually strive to incorporate advancements in our products to better serve our customers and provide solutions that ultimately put patient safety first.

Please do not hesitate to contact the Endosafe Product Management team at EndoPM@crl.com should you have any questions or concerns regarding our End-of-Life program.

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Sincerely,

Allen M. Rudis
Associate Director, Regulatory Compliance

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