June 24th, 2022

Dear Distribution Customer,

In February of 2022 Belimed contacted you regarding our concerns about reported OUT OF SPECIFICATION Belimed Protect® Neutral Non-Enzymatic (NNED) and Ophthalmic Detergents. We asked you to refrain from using any inventory from related lot numbers until we completed our investigation of this issue, due to a concern for product quality. We also worked directly with customer sites and provided replacement products to assist you in this effort.

At this time, we have completed our root cause analysis to determine why certain containers did not meet the specification for clarity. The analysis identified that a limited number of containers showed visible undissolved surfactant. A surfactant is a compound commonly found in soaps and detergents to assist in the cleaning process. Undissolved surfactant is easily identifiable as it appears as a gelatin-like substance when present and may cause the product to become cloudy. The cause of the undissolved surfactant has been corrected.

Regarding the existing inventory we asked you to place on hold, we have determined that this product is safe for use. Any stock you have remaining may be used provided they are checked for clarity prior to use. As product clarity is determined visually, this can be easily performed by the end user. This completes the action required by you to close this issue. We have also notified customer users directly regarding the issue resolution.

As with all Protect products, if you have any stock that shows the presence of visible contaminants, we request that you return them per the Returned Materials Authorization (RMA) process shared in our previous letter and below. Additionally, if you are uncomfortable using the product for any reason please contact Susan Harley at the contact information below.
PRODUCT RETURN PROCESS (RMA):

Please take the following steps to process any product returns and ensure continuous supply of the highest quality products to perform your work.

a. Remove products from your distribution center locations.
b. Document Part number, lot number and quantity of products for return. Send this information to consumablesquality.us@belimed.com to request Belimed return documentation which will include the Return Material Authorization (RMA) number, FedEx Account # (see below) and SHIP TO address. Since we will be replacing for free your affected inventory, the RMA will show a $0 credit. The return must be accompanied by the RMA paperwork.
c. Work with your facility shipping and receiving department to coordinate the return with Federal Express. The FedEx phone # is 1-800-814-9561. Depending on the amount to return, it will need to be shipped via small parcel truck or a palletized freight shipment. Your shipping/receiving teams should be able to coordinate this activity. You should use Fed Ex Account # 340997786 to charge the shipping costs. If you have any questions, please send them to consumablesquality.us@belimed.com.
d. Notify the Consumables Quality team at consumablesquality.us@belimed.com once the product is shipped.

We appreciate your understanding and patience as we worked through the issue. As mentioned previously we felt it important to err on the side of caution until we could fully investigate and determine the product’s safety and efficacy.

Should you have any questions, please contact your Belimed Account Manager, Susan Harley @ 843-925-9411, or send an email to consumablesquality.us@belimed.com.

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