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MediSense Products
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Dear Valued Customer:

Recently, Abbott Laboratories, MediSense Products discovered that counterfeit packaging for Precision QID[®] Blood Glucose Test Strips has entered the distribution channel. Since the identified product was repackaged by an unknown source, we cannot confirm that the repackaging was conducted in a manner consistent with Good Manufacturing Practices. In addition, we found that the counterfeit packaging contained several labeling inconsistencies. When such repackaging occurs, we are unable to guarantee the accuracy of the claims contained on the package labeling. The distributor who purchased and resold the affected product has begun a "distributor initiated" recall. The U.S. Food and Drug Administration (FDA) have been notified of the recall.

We became aware of the counterfeit packaging when a distributor returned it to us through our normal return goods process. Apparently, this distributor purchased the product from the alternate source market. Also known as the gray or diverted market, the alternate source market encompasses product purchased from any source other than the original manufacturer or an authorized distributor. Purchasing from the alternate source market provides the opportunity for potentially adulterated or misbranded product to enter the U.S. distribution channel, in violation of the Federal Food, Drug & Cosmetic Act. This unauthorized repackaging also violates the Federal Lanham Act and copyright laws.

Because we cannot be sure how the repackagers are handling, storing, packaging and/or distributing this repackaged product, Abbott Laboratories, MediSense Products cannot assure consumers and health care professionals of the quality and/or accuracy of the product/labeling purchased from the alternate source market.

We take the discovery of this counterfeit packaging very seriously. We have contacted the FDA and are working closely with them during their investigation of this issue. To minimize your risk of receiving compromised product, we recommend that you contact your distributor(s) and ask if they purchase any MediSense Blood Glucose Products from the alternate source market. Further, you may wish to request assurances from your distributors that the products you are purchasing as packaged are not from the alternate source market. We recommend that you purchase our product from those who purchase only directly from us. We believe this action is necessary to maximize the integrity of the health care supply chain.

Thank you for your cooperation and assistance. If you have any questions concerning this letter, please call 1-800-537-3575.

Sincerely,

John Landgraf
Corporate Vice President
Medical Products Group Quality Assurance

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