PRODIGY
diabetes care

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Prodigy Diabetes Care, LLC
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September 4, 2013

To all Patients, Caregivers, and Prodigy Diabetes Care Partners:

In March 2012 the United States FDA conducted an inspection of Prodigy Diabetes Care, LLC in Charlotte, NC. After Prodigy responded to the FDA's initial observations, the FDA issued a Warning Letter clarifying its position on these issues, and directing Prodigy to take certain actions and revise some of its procedures.

One issue raised by the FDA was Prodigy's process for reviewing and filing Medical Device Reports. As the Warning Letter indicates, the FDA regulation requires manufacturers to submit a MDR after it becomes aware of information that reasonably suggests that a device that it markets *may have caused* an injury. The FDA interprets the language "*may have"* very broadly, which is the point it clarified in the letter to Prodigy. Since February, Prodigy has reviewed all complaints received during the years 2011-2013, under the guidance set forth in the FDA letter, and filed MDRs for those incidents.

The complaints received by Prodigy are similar to those received by all manufacturers, which you can view at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmdr/search.CFM. Regardless of brand, patients occasionally experience "out of normal" readings from their blood glucose systems. Whether the cause be contaminated strips due to temperature, batteries, improper storage or handling of strips, or otherwise, all manufacturers receive reports that their devices "may have been a factor" in an injury.

The second area addressed by the FDA was Prodigy's inspection of goods prior to release to customers. The FDA sets a measurable standard by which blood glucose systems are tested. **All of Prodigy's test strips released for distribution met the FDA standard**. **No test strips have ever been released that failed to meet the FDA standard.** The FDA letter addressed additional measures that Prodigy included in its internal procedures. Upon receipt of the notification by the FDA, though the prior testing revealed that the product met FDA standards, Prodigy conducted further testing of the lots identified, and confirmed that all of the released product met the requirements of the FDA.

This year Prodigy has conducted a regulatory assessment by an independent auditor, a former FDA inspector, to audit, review and revise its procedures and training in these areas, and others, to ensure that our operations are aligned with the FDA's guidance. Prodigy assures you that this is attention to improvement is an ongoing effort to ensure full compliance.

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Prodigy's goal is to provide accurate and reliable products at a good value. Just as important to us as the FDA's input is feedback from persons who use our products day after day. We welcome your input, and will work hard to address your concerns.

Richard Admani
Chief Operations Officer