

August 7, 2006

**VIA FEDERAL EXPRESS OVERNIGHT**

Division of Dockets Management  
Food and Drug Administration  
U.S. Department of Health and Human Services  
5630 Fishers Lane  
Room 1061 (HFA-305)  
Rockville, MD 20852

**CITIZEN PETITION**

To Whom It May Concern:

The undersigned submits this petition under Sections 201 and 502 of the Federal Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. §§ 321(m) and 352, respectively), for which authority has been delegated to the Commissioner of Food and Drugs ("Commissioner") under Volume II, §1410.10 of the Food and Drug Administration ("FDA") Staff Manual<sup>1</sup> to request the Commissioner to order Abbott Laboratories to cease immediately its false and misleading claim that its MediSense Precision Xtra Advanced Diabetes Management System has "Auto Calibration."

Abbott Laboratories ("Abbott") manufactures a number of products that are part of its MediSense Precision Xtra Advanced Diabetes Management System. These products include the Precision Xtra Blood Glucose Monitor and Precision Xtra Blood Glucose Test Strips, among other items. Both the labeling on the box for the test strips and the User's Manual for the glucose monitor, as described in more detail below, refer the patient to websites which directly lead to Abbott's false and misleading claims regarding "auto calibration" and "no coding required." The product is not, in fact, automatically calibrated, and the false and misleading claim that it is can lead to serious patient confusion and serious adverse health effects for diabetic patients as a result of such confusion.

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<sup>1</sup> The directions on the FDA website for submitting a Citizen Petition cite to 21 CFR Part 5.10 as the source for the authority delegated to the Commissioner to take action in response to this petition. According to the April 2, 2004 Federal Register, 21 CFR Part 5.10 was removed and replaced with an alternative source for such authority, § 1410.10 of the Internet-based FDA Staff Manual Guide ("SMG").

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## A. ACTION REQUESTED

The undersigned requests that the Commissioner order Abbott to remove from its website and any other labeling and/or printed materials the false and misleading statements of "Auto Calibration" and "no coding required" associated with its MediSense Precision Xtra Advanced Diabetes Management System.

## B. STATEMENT OF GROUNDS

### 1. Legal Grounds

As noted above, the label on the Precision Xtra Test Strips as well as the User's Guide for the Precision Xtra Glucose Monitor refer patients to a website where the false and misleading claim of "Auto Calibration" is prominently displayed. Specifically, on the back of the Precision Xtra Test Strips box, Abbott refers the patient to the AbbottDiabetesCare.com website. See Exhibit A (copy of labeling on Abbott MediSense Precision Xtra Test Strips box). On the back of the Precision Xtra Glucose Monitor's User's Guide following page 89, Abbott refers the patient to MediSense.com. See Exhibit B (copy of User's Guide). Both of these websites contain a link to a web page for the Precision Xtra products, on which the false and misleading "auto calibration" and "no coding required" claims are made. See Exhibit C.<sup>2</sup> Furthermore, on this website, under the heading of "Auto Calibration," Abbott states as follows: "Simply insert calibrator into the strip port; no coding required." Id.

21 U.S.C. § 352 governs FDA jurisdiction over false and misleading labeling. The term "labeling" in § 352 is broadly defined in the plain wording of 21 U.S.C. § 321(m) as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."<sup>3</sup> As explained above, Abbott's labeling refers the patient to a website which contains a false and misleading claim. These materials collectively constitute "labeling" under the broad definition contained in 21 U.S.C. § 321(m), and FDA therefore has the authority under the FDCA to stop such false and misleading labeling.<sup>4</sup>

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<sup>2</sup> Abbott Laboratories, <http://www.diabeteshealthconnection.com/products/monitors/precision/precisionxtra.aspx> (last visited August 7, 2006).

<sup>3</sup> Although the language of the statute is clear, the United States Supreme Court addressed this issue in ruling that both the actual label for a drug and literature which supplemented the label met the broad definition of "labeling" under the FDCA. Kordel v. United States, 335 U.S. 345, *reh'g denied*, 335 U.S. 900 (1948), *reh'g denied*, 336 U.S. 911 (1949).

<sup>4</sup> 21 C.F.R. § 809.10 provides specific guidance on what labels for *in vitro* devices should contain.

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## **2. Factual Grounds**

Abbott's claims that its Precision Xtra Glucose Monitor has "auto calibration" and "no coding required" are false and misleading. The FDA should order Abbott to remove these claims from its website and any other labeling and/or printed materials immediately, as it is likely to cause considerable patient confusion which can, in turn, lead to serious public harm.

"Auto calibration" and "no coding" mean that a glucose monitor does not require calibration (also known as coding) by the user, whether by selecting a proper code or, in this case, by inserting a calibration (coding) strip. Rather, with auto calibration, the calibration is performed automatically when a new test strip or strip disc is loaded into the meter. Without auto calibration, patients are required to calibrate their machines either prior to or upon using a new box of test strips in order to account for differences in the reagent-strip manufacturing lots.

The advent and use of auto calibration monitors is of great significance to diabetes patients. It increases accuracy in glucose testing and reduces the chances for human error. Patients who use auto calibration systems no longer have to worry about forgetting to calibrate their machines when they open a new bottle of test strips and obtaining inaccurate readings as a result of the failure to do so. In fact, it has been argued that manual calibration should be avoided in the next generation of blood glucose meters.<sup>5</sup>

Bayer HealthCare LLC ("Bayer"), on whose behalf this petition is submitted, distributes and markets an innovative product with automatic calibration called the Ascensia Contour Blood Glucose Monitoring System.<sup>6</sup> This unique Bayer system is different from other single strip systems because it does not require the user to code the meter. The coding is performed automatically when the meter is turned on by the insertion of an Ascensia Contour/Microfill Test Strip.

In contrast to the Bayer Ascensia Contour system, the Abbott Precision Xtra Glucose Monitor is not automatically calibrated. As the Abbott User's Guide indicates on page 22, manual calibration is, in fact, required. Furthermore, the Abbott User's Guide requires that that patient verify that the lot number matches on the package insert, the calibrator, and the test strip foil. As a result, if patients fail to use the appropriate calibrator corresponding to the test strips being used, their meters may be miscoded as a consequence, and they may obtain inaccurate

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<sup>5</sup> Kilo, Charles S., et al, Evaluation of a New Blood Glucose Monitoring System with Auto-Calibration, Diabetes Technology and Therapeutics, Vol. 7, No. 2, 283-94 (2005). See Exhibit D.

<sup>6</sup> In addition, Bayer has a multi-strip blood glucose monitoring system called the Ascensia Breeze, which also does not require the user to code the meter. Coding is performed automatically when a new test strip disc is loaded into the meter.

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blood glucose results. By use of the term "auto calibration," however, patients are led to believe that they need not calibrate the Abbott product. The consequences of such miscoding to a diabetes patient's health cannot be underestimated. Researchers have acknowledged the serious adverse health events that can result when blood glucose results are obtained from miscoded meters.

In a 2005 study, Dr. Charles Kilo and several colleagues noted that the problem of miscoding is widely recognized among users of manually coded meters.<sup>7</sup> Kilo cited to two recent studies, each of which independently found that 16% of the subjects had incorrectly coded their meter to the lot of test strips used.<sup>8</sup> One study by Dr. Charles Raine in 2003 examined the glucose meter code and corresponding glucose strip codes of 201 patients with diabetes.<sup>9</sup> Dr. Raine concluded that a considerable number of these patients failed to use glucose meters properly and that clinical data based on such data can result in adverse events.<sup>10</sup> Similar findings were reported in the other study by Dr. Gunn Kristensen and several colleagues cited by Dr. Kilo.<sup>11</sup> The findings of Dr. Kristensen and his colleagues showed that 16% of subjects had incorrectly coded their meters to the lot of test strips.<sup>12</sup>

John Baum and several colleagues determined that, when certain meter code number settings of two blood glucose monitoring systems were used in conjunction with test strips having code numbers that did not match, statistically and clinically inaccurate results were obtained.<sup>13</sup> They concluded that these results showed the importance of using a system with an automatic coding feature. The use of an automatic coding system eliminates an important potential cause of inaccurate results that can lead to unnecessary and sometimes dangerous clinical results.<sup>14</sup>

In a late 2000 study, Dr. Richard Bergenstal and several colleagues noted that, while patient self-monitoring of blood glucose was recognized as the most significant breakthrough in diabetes since insulin, the value of this discovery was significant only if it was done correctly,

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<sup>7</sup> Kilo, supra note 5, at 284.

<sup>8</sup> Id.

<sup>9</sup> Raine, Charles H., Self-Monitored Blood Glucose: A Common Pitfall, Endocrine Practice, Vol. 9, No. 2, 137-39 (March/April 2003). See Exhibit E.

<sup>10</sup> Id. at 137.

<sup>11</sup> Kristensen, Gunn B.B., et al, Standardized Evaluation of Instruments for Self-Monitoring of Blood Glucose by Patients and a Technologist, Clinical Chemistry 50, 1068-1071 (2004). See Exhibit F.

<sup>12</sup> Id. at 1070.

<sup>13</sup> Baum, John M., et al, Improving the Quality of Self-Monitoring Blood Glucose Measurement: A Study in Reducing Calibration Errors, Diabetes Technology & Therapeutics, Vol. 8, No. 3, 347-57 (2006). See Exhibit G.

<sup>14</sup> Id.

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and accurate results were obtained.<sup>15</sup> The study, among other things, highlighted the importance of technical considerations related to meter calibration.<sup>16</sup>

FDA has also acknowledged the problems associated with miscoding of glucose meters. According to a draft document issued in 1997, the FDA has received many reports of problems with blood glucose meters since 1984.<sup>17</sup> A large number of these problems have been attributed to users' incorrect techniques or operating procedures.<sup>18</sup> In this report, the FDA referred to an FDA-funded human factors study which found that blood sampling was identified as having the greatest potential for error.<sup>19</sup> Finally, the FDA issued a paper in 2004 indicating that there are more adverse event reports received on glucose monitors than on any other *in vitro* device.<sup>20</sup>

In the wake of such considerable evidence pointing to the importance of the accuracy of glucose monitor readings and the adverse health effects in the absence of such, we respectfully request that the FDA act immediately to stop Abbott's false and misleading use of the term "Auto Calibration" to describe its MediSense Precision Xtra Advanced Diabetes Management System.

Abbott may claim in response to this petition that its User's Guide on page 22 diffuses any concern about its auto calibration claim by stating that these instructions tell the patient to calibrate the monitor "[w]hen you use the monitor for the first time" and "[e]ach time you open and use a new box of blood glucose or blood  $\beta$ -Ketone test strips." Such an argument is unpersuasive, and the FDA should reject it. This very description in the User's Guide proves the undersigned's point. As the User's Guide states, calibration is actually required. Thus, Abbott's use of the phrases "Auto Calibration" and "no coding required" are clearly false and misleading. The Abbott Precision Xtra Glucose Monitor does not automatically calibrate once the strip is inserted. Accordingly, Abbott should be required to discontinue making all of these claims on its website and in any other labeling and/or printed materials.

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<sup>15</sup> Bergenstal, Richard, et al, Identifying Variables Associated with Inaccurate Self-Monitoring of Blood Glucose: Proposed Guidelines to Improve Accuracy, *The Diabetes Educator*, Vol. 26, No. 6, 981-89 (Nov./Dec. 2000). See Exhibit H.

<sup>16</sup> Id. at 985-86.

<sup>17</sup> Review Criteria Assessment of Portable Blood Glucose Monitoring In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase or Hexokinase Methodology, Draft Document, FDA Clinical Chemistry and Toxicology Devices Branch, Division of Clinical Laboratory Devices, Office of Device Evaluation (Released for comment on Feb. 28, 1997). See Exhibit I.

<sup>18</sup> Id.

<sup>19</sup> Id.

<sup>20</sup> Gutman, Steven I., et al, Consumers Report Glucose Meter Problems to FDA, *Diabetes Technology and Therapeutics*, Vol. 6, No. 6, 767-79 (2004). See Exhibit J.

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### C. ENVIRONMENTAL IMPACT STATEMENT

As the requested action is categorically excluded under 21 C.F.R. § 25.30, neither an environmental assessment nor an environmental impact statement is required.

### D. ECONOMIC IMPACT STATEMENT

Economic impact information will be submitted only when and if requested by the Commissioner following review of this petition, in accordance with 21 C.F.R. § 10.30.

### E. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

**By: MANATT, PHELPS & PHILLIPS, LLP**

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