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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

WITHDRAWAL OF CITIZEN PETITION – DOCKET #2006P-0313

To Whom It May Concern:

On August 7, 2006, Bayer HealthCare LLC (“Bayer”) submitted through the undersigned counsel a Citizen Petition requesting that the Commissioner of FDA order Abbott Laboratories to cease immediately its false and misleading claim that its MediSense Precision Xtra Advanced Diabetes Management System has “Auto Calibration.” On August 8, 2006, you assigned docket number 2006P-0313 to the petition.

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 Abbott MediSense Precision Xtra Advanced Diabetes Management System 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.¹

In the Citizen Petition, we specifically requested that the Commissioner order Abbott to remove from its website and any other labeling and/or printed materials the false and misleading

¹ Bayer distributes and markets an innovative product with automatic calibration called the Ascensia Contour Blood Glucose Monitoring System which, unlike the Abbott product in question, does, in fact, have automatic calibration. This unique Bayer system is different from other single strip systems because it does not require the user to code the meter. Rather, the coding is performed automatically when the meter is turned on by the insertion of an Ascension Contour/Microfill Test Strip.

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statements of "Auto Calibration" and "no coding required" associated with its MediSense Precision Xtra Advanced Diabetes Management System.

We have decided to pursue through other means within FDA the same procedural relief that we sought by filing this Citizen Petition. Accordingly, in order to facilitate the expeditious review of Bayer's claims against Abbott through these other means and to avoid duplication of the agency's efforts in responding to this serious matter, we hereby withdraw this petition. As stated in 21 C.F.R. § 10.30(g), such withdrawal may be accomplished without agency approval and is without prejudice to resubmission at any time before the Commissioner rules on the petition, as is the case here. Such withdrawal is also, of course, without prejudice to pursuing the relief Bayer plans to seek through other means within the FDA.

Please do not hesitate to contact us if you have any questions about the withdrawal of this petition. We would appreciate if you would confirm this withdrawal in writing to us as soon as possible.

Sincerely,

By: MANATT, PHELPS & PHILLIPS, LLP

R. Bruce Dickson / GW

R. Bruce Dickson, Esq.

Gregory W. Fortsch, Esq.

700 12th Street, NW

Suite 1100

Washington, DC 20005

(202) 585-6500

rbdickson@manatt.com

gfortsch@manatt.com

Counsel for Bayer HealthCare LLC

cc: Terri Garvin, FDA Office of *In Vitro* Diagnostic Device Evaluation and Safety (via facsimile only)

James L. Woods, FDA Office of *In Vitro* Diagnostic Device Evaluation and Safety

Carol C. Benson, FDA Office of *In Vitro* Diagnostic Device Evaluation and Safety

Mary K. Engle, Federal Trade Commission, Consumer Protection Bureau, Advertising Practices Division