U.S. Food and Drug Administration

Medical Devices

FDA/CDRH Public Meeting: Blood Glucose Meters - March 16-17, 2010

POST MEETING INFORMATION:

Slides are available on the Diabetes Technology society website [1] [2]

Copies of the transcripts from this meeting are posted below under the section marked "Transcripts".

Background

Glucose meters are used by millions of people with diabetes every day. These devices have become smaller, faster, and more accurate over the past 3 decades and now allow for better glycemic control by diabetics than in the past. Glucose meters are not only used by diabetics at home, they are also used by healthcare providers in a variety of settings such as hospitals, emergency response units, nursing homes, and physicians' offices.

Some in the clinical and patient communities have questioned whether the current accuracy standards for blood glucose meters are acceptable and have challenged FDA to require tighter performance standards. Blood glucose meters are being used in clinical settings and at home in ways that have not been approved as safe and effective for these products. For example, glucose meters are increasingly being used to achieve tight glycemic control despite the fact that these devices have not been approved for this use. There is currently no consensus that blood glucose meters currently on the market are accurate enough to be used in this way. Still, other stakeholders believe the current analytical performance of glucose meters is adequate and that there is no evidence to support the need for higher standards. Other factors affecting the performance of blood glucose meters include administered drugs, common physiological conditions (such as diabetic ketoacidosis), and user-interface issues. For example, the administration of therapies containing maltose, which are commonly prescribed to patients in the hospital, have resulted in falsely elevated glucose results.

In response to the issues identified above, the FDA is advocating for tightening the system accuracy criteria specified by current glucose meter standards, and is considering whether FDA review criteria for these devices should be changed to promote the public health. The FDA is interested in hearing from clinical experts about the clinical requirements for blood

glucose meter accuracy and precision, and the benefits and risks of using glucose meters to achieve and maintain tight glycemic control. The appropriate analytical and clinical accuracy requirements for blood glucose meters will be discussed during this meeting, as well as the potential benefits and challenges of meeting those requirements. We are seeking participation from all stakeholders including, but not limited to: physicians, nurses, healthcare providers who work in intensive care settings, industry, diabetes educators, professional societies, consumers and patient advocate groups.

Date, Time and Location

The meeting was held on March 16 (9:00 a.m. to 5:00 p.m.) and March 17 (9:00 a.m. to 3:40 p.m.) at the Hilton Washington DC North/Gaithersburg Hotel at:

Hilton Washington DC North/Gaithersburg Hotel
620 Perry Parkway
Gaithersburg, MD 20877

Transcripts

- Transcript for March 16, 2010 [4]
- Transcript for March 17, 2010 [5]

Public Comments

Refer to the Federal Register Notice for instructions on how to submit comments about the topics discussed at this meetin

To view the comments go to http://www.regulations.gov [6] and search by the key word: "FDA-2009-N-0604." If you have questions about the posted comments please call the Dockets Management Public Room at (301) 827-6860.

Tentative Agenda

DAY 1: Tuesday, March 16, 2010

7:30 a.m. **Registration in Grand Foyer**
8:00 a.m. **Continental Breakfast in Grand Foyer**
9:00 a.m. **FDA Welcome**
Courtney Harper, Ph.D., Director, Division of Chemistry and Toxicology Devices, Center for Devices and Radiological Health, Silver Spring, Maryland
9:05 a.m. **Opening Remarks**
Jeffrey E. Shuren, M.D., J.D., Director, Center for Devices and Radiological Health

Session 1: Clinical Accuracy Requirements for Blood Glucose Meters

9:15 a.m. **Moderator's Introduction of Session 1**
William L. Clarke, M.D. University Of Virginia School Of Medicine, Charlottesville, Virginia
9:25 a.m. **FDA Perspective: FDA Evaluation of Point of Care Blood Glucose Meters**
Patricia Bernhardt, M.T.(ASCP), Office of in Vitro Diagnostic Device Evaluation and Safety
9:50 a.m. **Analytical Performance of Blood Glucose Meters: State of the Art**
Mitchell Scott, Ph.D., Washington University School of Medicine, St. Louis, Missouri
10:15 a.m. **Clinical Perspective: Clinical Need for Tighter Performance Requirements**
David B. Sacks, M.D., M.B., Ch.B., Harvard Medical School and Brigham and Women's Hospital, Boston, Massachusetts
10:40 a.m. Break
11:00 a.m. **Clinical Perspective: Clinical Needs Relative to Insulin Dosing**
Marc Breton, Ph.D., University of Virginia, Charlottesville, Virginia
11:25 a.m. **Industry Perspective: Tighter Performance Criteria for Blood Glucose Meters; Are They Needed?**
Steve Brotman, M.D., J.D., Advanced Medical Technology Association (AdvaMed)
11:50 a.m. **Industry Perspective: Tighter Performance Criteria Are Achievable and Appropriate**
Barry Ginsberg, M.D., Ph.D., Diabetes Consultants, Wyckoff, New Jersey
12:15p.m. Lunch on your own
1:30 p.m. **Session 1 Panel Discussion**
Added panel members: David C. Klonoff, M.D., F.A.C.P., Mills-Peninsula Health Services, San Mateo, California; Ellen H. Ulman, MSW, Close Concerns, Boca Raton, Florida; Alberto Gutierrez Ph.D. and; Courtney Harper, Ph.D.

Session 2: Blood Glucose Meter Performance, Interferences and Limitations

2:30 p.m. **Moderator's Introduction of Session 2**
Gary L. Myers, Ph.D., Division of Laboratory Sciences at the Centers for Disease Control and Prevention, Atlanta Georgia
2:40 p.m. **FDA Perspective: Public Health Notification: Potentially Fatal Errors with GDH-PQQ Glucose Monitoring Technology**
Courtney Harper, Ph.D.
3:05 p.m. Break in Grand Foyer
3:20 p.m. **Analytical Interferences and Physiological Limitations of Blood Glucose Meters**

Ken Ervin, Ken Ervin Consulting Services, Brentwood, California
3:45 p.m. **Industry Perspective: Barriers to Overcoming Interferences and Limitations**
Alan Cariski, M.D., J.D., FACP, FACE, LifeScan, Inc.
Mike Flis, Roche
4:10 p.m. **Session 2 Panel Discussion**
5:00 p.m. **Day 1 Closing Remarks**
Courtney Harper, Ph.D.

DAY 2: Wednesday, March 17, 2010

8:00 a.m. **Continental Breakfast in Grand Foyer**
9:00 a.m. **Day 2 Welcome**
9:10 a.m. **Keynote Address: Liability Issues In The Use of Blood Glucose Meters**
Jack R. Bierig, Sidley Austin LLP, Chicago, Illinois

Session 3: Tight Glycemic Control

9:40 a.m. **Moderator's Introduction of Session 3**
Irl B. Hirsch, M.D., University of Washington Medical Center, Seattle, Washington
9:50 a.m. **FDA Perspective: Regulatory Challenges for Safe use of Blood Glucose Meters in Hospital Settings**
Carol Benson, M.S., M.T.(ASCP), Division of Clinical Chemistry and Toxicology Devices
10:15 a.m. **Payer Perspective: Reimbursement Issues Associated with Glycemic Control**
Jim Rollins, M.D., Ph.D., MSHA, Centers for Medicare and Medicaid Services, Baltimore, Maryland
10:40 a.m. Break in Grand Foyer
11:00 a.m. **Advantages of Tight Glycemic Control in Hospital Settings**
Richard Bergenstal, M.D., International Diabetes Center at Park Nicollet, Minneapolis, Minnesota
11:25 a.m. **Why Tight Glycemic Control May Not be Appropriate in Hospital Settings**
Dieter Mesotten, M.D., Ph.D., University Hospitals Leuven, Belgium
11:45 a.m. **Current Practice and Experiences with Tight Glycemic Control in Hospital Settings**
Irl B. Hirsch, M.D.
12:10 p.m. Lunch on your own
1:30 p.m. **Session 3 Panel Discussion**
Additional panel member: Patricia Beaston, M.D., Ph.D., Office of Device Evaluation
2:30 p.m. **How Meters are Used at Home and How Consumers Choose Meters**
Ellen H. Ullman, MSW, Close Concerns, Boca Raton, Florida
2:55 p.m. **Risk Mitigation in Hospitals**
Dawn Hanson, MS MLS(ASCP), DLM, St. Agnes Hospital, Baltimore, Maryland
3:20 p.m. **Wrap-up; Where do we go from here?**
David C. Klonoff, M.D., F.A.C.P.
3:30 p.m. **Closing Comments**
Alberto Gutierrez, Ph.D.
3:40 p.m. **Meeting Adjourns**

Contact Us

The workshop organizer may be contacted at:

Arleen Pinkos
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue WO-66-5618
Silver Spring, MD 20993
Phone: (301) 796-6152
email: Arleen.Pinkos@fda.hhs.gov[7].

Links on this page:

1. http://www.diabetestechnology.org/press_releases.shtml
2. http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm
3. http://edocket.access.gpo.gov/2010/2010-742.htm
4. http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM208598.pdf
5. http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM208601.pdf
6. http://www.regulations.gov/

7. http://20100604225126/mailto:Arleen.Pinkos@fda.hhs.gov