AMDM / FDA – OIVD Submission Workshop

Tuesday, April 20-Wednesday, April 21, 2010

White Flint Amphitheater
Bethesda North Marriott Hotel and Conference Center
5701 Marinelli Road
N. Bethesda, Maryland

Day 1 – April 20, 2010 (Tuesday)

8:00 - 9:00 AM ***Registration and Breakfast***

9:00 - 9:15 ***Welcome and Introduction***
- Judi Smith, President, AMDM

9:15 – 10:00 ***Introduction to OIVD***
- Don St. Pierre, Deputy Director, OIVD

10:00 – 10:15 ***Break***

10:15 - 10:45 ***Small Manufacturers Assistance (DSMICA)***
- Joe Tartal, DSMICA Branch Chief, Technical Assistance Branch

10:45 – 11:15 ***Registration and Listing***
- David Gartner, Program Analyst, OC

11:15 – 12:15 PM ***When to Submit (or not) a 510(k), that is the Question!***
- Heather Rosecrans, Director, 510(k) Staff, ODE

12:15 - 1:30 ***Networking Lunch* w*ith the FDA Staff***

1:30 – 2:00 ***Special and Abbreviated 510(k) and Add-to-Files***
- Doug Rheinheimer, Scientific Reviewer, Division of Chemistry and Toxicology Devices, OIVD

2:00 – 3:30 ***510(k) Decision Summaries:***
A Reviewer's Perspective with Case Studies
- Stephanie Akselrod, Reviewer, Division of Microbiology Devices, OIVD

Software in the World of In Vitro Diagnostics
- Andrew Grove, Ph.D., Scientific Reviewer, Division of Microbiology Devices, OIVD
- Eugene Reilly, Scientific Reviewer, Chemistry and Toxicology Devices, OIVD

3:30– 3:45 ***Break***

3:45 – 4:15 ***Molecular Diagnostics 510(k) Submissions***
- Kellie Kelm. Scientific Reviewer, Division of Chemistry and Toxicology Devices, OIVD

4:15 – 4:45 ***De Novo***
- Donna Roscoe Ph.D., Scientific Reviewer, Microbiology Devices, OIVD

4:45 – 5:15 ***510(k) Combination Product & Companion Diagnostics***
- Joseph Milone, PhD, Biologist, OCP

5:15- 5:30 ***Strategies for Working with FDA***
- Judi Smith, President, AMDM

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Day 2 – April 21, 2010 (Wednesday)

8:00-9:00 AM ***Registration and Breakfast Buffet***

9:00 – 9:30 ***PMA Process***
- Zivana Tezak, Associate Director for Science and Technology
- Kate Simon, Scientific Reviewer, Division of Microbiology, OIVD
- Sally Hojvat, Director of the Microbiology Division

9:30 - 10:00 ***Bioresearch Monitoring (BIMO)***
- Veronica Calvin, M.A., Biologist Division of Bioresearch Monitoring, OC

10:00 - 10:15 ***Break***

10:15 – 10:45 ***Health Hazard Evaluation/Recalls***
- Murray Malin, M.D., Medical Officer, DOEA, OC

10:45 – 11:15 ***Interacting with Compliance/Case Management***
- Tara Goldman, Biologist, Consumer Safety Officer, OIVD

11:15 – 11:45 ***Quality System Regulations***
- Tonya Wilbon, Biologist, Consumer Safety Officer, OIVD

11:45 – 12:15 PM ***Import/Export***
- Laurence Spears, Deputy Director for Regulatory Affairs, Office of Compliance

12:15- 1:30 PM ***Lunch With the FDA Staff***

1:30 – 2:45 ***Frequently Asked Questions Submitted by the Audience***
- Don St. Pierre, Deputy Director
- James Woods, OIVD Division Director

2:45 -- 3:00 ***Break***

3:00 – 4:15 ***FDA's New Statistical Guidance Document: An Interactive Session***
- Kristen Meier, Ph.D., OSB

4:15 – 4:45 ***Special Topics – Hematology: Premarket and Postmarket Findings for Home-Use PT/INR devices***
- Leonthena Carrington, Associate Director Hematology and Pathology Division.

4:45 – 5:00 ***Wrap Up***

Please travel safely. We hope to see you again next year!