

IVDMIA
guidance 2006D-
0347

Rec'd 5/29/07

MEMORANDUM OF MEETING
May 8, 2007
3:00 p.m. – 4:00 p.m.
Parklawn Building

Attendees: FDA: Susan Winckler, Janet Woodcock, Daniel Schultz, Steve Gutman, Joseph Grogan, Ann Wion, Laura Epstein, Sharon Mayl, Courtney Harper (by phone), Sara Kotler, Alberto Gutierrez, Martin Ruta, Sally Hojvat, Diane Maloney, Mary Pastel, Zivana Tezak, Kathleen Quinn, and Kristy Moran

21st Century Medicine Coalition:

- Randy Scott, Ph.D., Chairman and CEO, Genomic Health, Inc.
- Kevin Conroy, President and CEO, Third Wave Technologies
- Orkideh Malkoc, Associate Director of Public Policy, Genetic Alliance
- Jeff Gibbs, Consultant, Hyman, Phelps, & McNamara P.C.
- Paul Kim, Consultant, Foley, Hoag, & Elliot, L.L.P.

Subject: The purpose of the meeting was to follow-up with members of the 21st Century Medicine Coalition to discuss FDA's draft guidance documents entitled, "Draft Guidance for Industry and FDA Staff; Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions" and "Draft Guidance for Industry, Clinical Laboratories, and FDA Staff; In Vitro Diagnostic Multivariate Index Assays (IVDMIA)" and related issues.

Highlights:

- In follow-up to a meeting on December 14, 2006 between FDA and representatives of the Coalition for the 21st Century Medicine, the Coalition provided information about ASR and IVDMIA products that would be affected if FDA's ASR and IVDMIA Draft Guidances were implemented as written.
- The Coalition shared their concerns and concerns of other stakeholder groups, and provided the following alternatives to the ASR Draft Guidance:
 - Eliminate the "multiple moiety" and "multiple marker" language.
 - ASRs could be placed into Class II as ASRs exempt from premarket notification, but subject to design controls and special controls.
 - Self-certification, instead of requiring clearance or approval of ASRs. If clearance is required, the level of data required by FDA should be limited to that supporting the analytical claims.
 - Grace period – any changes to the existing ASR regulations should include a grace period.
- The Coalition's comments to the IVDMIA Draft Guidance:

2006D-0347

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- FDA/HHS should determine best framework for regulation (by enhancing and strengthening CLIA and considering a voluntary registry to obtain information about tests).
- FDA should proceed with notice and comment rulemaking and consider alternatives and input from stakeholders.
- The Coalition's comments if FDA proceeds with regulation of IVDMIAs as devices:
 - Limit the device definition to the algorithm (to provide clarity)
 - Base regulation on risk and market size
 - Define transition period

Action Items:

- *None.*

/s/

Kristy Moran
Policy Analyst
FDA Executive Secretariat