Update on Rapid HIV Tests

CLIAC
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Purpose of This Presentation

To inform CLIAC of progress made toward the approval of new rapid HIV tests since the last meeting

Discussion of Submission Status

- FDA is prohibited from releasing any information related to submissions, as this is considered proprietary
- Limited to discussion of public information only, or information authorized for release by the applicant

Public Information Related to Rapid HIV Test Submissions

- On May 1, 2002, MedMira Incorporated announced, “the completion of a site inspection of the Company's facilities in Halifax by the U.S. Food and Drug Administration in connection with MedMira's application for Pre-Market Approval of its Reveal™ Rapid HIV Test.” (http://www.medmira.ca/press_releases_f.htm)
- In addition, MedMira has given FDA permission to disclose that they received an approvable letter for their PMA on May 24, 2002

Public Information Related to Rapid HIV Test Submissions, cont.

- On May 13, 2002, OraSure Technologies, Inc, announced, "it has received notification from the U.S. Food and Drug Administration ('FDA') that the OraQuick® Rapid HIV-1 Antibody Test is approvable… Final approval is subject to the Company submitting product labeling and resolving specific validation and design control issues identified during FDA's recent pre-approval inspection of the Company's manufacturing facilities…"

  (http://www.orasure.com/news/default.asp?art_id=185)