Summary of 3/10/06 BPAC Session: Proposed Studies to Support the Approval of Over-the-Counter (OTC) Home-Use HIV Test Kits

CLIAC

September 20, 2006

Elliot P. Cowan, Ph.D.
Chief, Product Review Branch
Division of Emerging and Transfusion Transmitted Diseases
FDA/CBER/OBRR

Purpose of this Session

- Follow-up to 11/3/05 BPAC discussion of what would be needed to support approval of home-use HIV test kits
- FDA developed set of proposed studies and sought concurrence on its proposal from BPAC

Overview of Proposed Studies

- Studies to identify potential users of the test
- Phase I studies
- Phase II studies
- Phase III studies
- Additional recommendations on informational materials, counseling, testing, and referral

Studies to Identify Potential Users of the Test

- Potential users of the test should be identified by means of qualitative research
- Clinical trial study populations should reflect the demographics of those users identified in these studies

Phase I Studies

- Objectives
  - To establish the inherent sensitivity and specificity of the test
  - To demonstrate that the test is capable of withstanding operational stress
- Performed by individuals trained in the use of the test

Phase II Studies (Observed)

- Objective: To evaluate in a controlled setting
  - Effectiveness and safety of sample collection by untrained potential users
  - Ability of untrained potential users to perform test properly
  - Ability of untrained potential users to read and interpret test results
  - Performance of test in hands of untrained potential users
  - Reactions to test results by untrained potential users
- Expected performance
  - Sensitivity and specificity $\geq$95% (lower bound of 95%CI)

Phase III Studies (Unobserved)

- Objectives:
  - Evaluate performance of the test (sensitivity and specificity) in the hands of untrained potential users
  - Evaluate reactions of study participants to their test results
  - Validate ability of informational materials to:
    - » Communicate the proper use of the test
    - » Communicate test limitations
    - » Have study participant seek follow-up testing and referral to care
    - » Effectively provide a route to counseling
  - Validate the counseling system
- Expected performance
  - Sensitivity and specificity $\geq$95% (lower bound of 95%CI)

BPAC Discussion

- BPAC voted unanimously in favor of proposed Phase I and Phase II studies, and in favor of most stringent proposed Phase III studies
- Concern expressed that particular groups of end-users will be left out of clinical trials if sponsor left to decide
  - FDA should have a role in specifying the makeup of clinical trial participants
  - Take into account low income, gender, minorities, e.g.

Additional Recommendations

- Labeling to clearly communicate need to read informational materials prior to conducting test
- The informational materials should be easy to comprehend by potential users of test
- Informational materials must clearly communicate expected performance of test kit based on clinical studies, including number of false positive and false negative results observed
- Informational materials must clearly communicate the limitations of window period testing

Additional Recommendations, cont.

- Informational materials must clearly communicate actions to be taken in the event of a reactive test result
- Clear and convenient methods for follow-up testing and referral must be established and communicated in informational materials
- Counseling must be accessible by means appropriate to potential desired users, be available at any time, and counseling information must be clearly communicated in informational materials

Next Steps

- Work with CDC to identify groups that should be included in clinical trials to ensure that needs for testing are met
- Work with sponsors to evaluate their proposals for studies supporting approval of their tests for home use
- Identify strategies for post-market surveillance of home-use HIV test kit performance