Office of Generic Drugs contribution to the PEPFAR program

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Agenda

- Nuts and Bolts of PEPFAR
- PEPFAR Background Information
  - What is PEPFAR
  - PEPFAR Goals
  - Who does PEPFAR serve
- OGD Approval Process
  - Differences
  - OGD's Contributions

Purpose of PEPFAR in a nutshell as it relates to the approval of drug products

- To tentatively approve safe and effective drug products in an expedited manner without compromising review standards.
- Tentatively approved products are eligible for purchase with appropriations from the PEPFAR program

What is PEPFAR?

- Presidents Emergency Plan For Aids Relief
  - 5 year program
  - 15 Focus countries
  - $15 billion through 2008
  - PTC: prevention, treatment and care

PEPFAR Timeline

- Announced during State of the Union address January 28, 2003
- Legislative authority for program May 27, 2003
- January 2004: appropriations provided for program
- Summer 2004: First Generic submission
- March 2006: 16 approved ANDAs and NDAs

Focus Countries

- Botswana, Cote d Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Vietnam and Zambia
- 120 countries worldwide

Where the program stands December 2005

- Supporting 800 ART sites
- Treatment of 400,000 individuals(up from approx 25,000 in 2003)
- In Botswana and Uganda the program has already exceeded treatment goals for the 5 year plan
- 70,000 patients supported in 17 other nations outside of focus countries

PEPFAR Purchasing Requirements

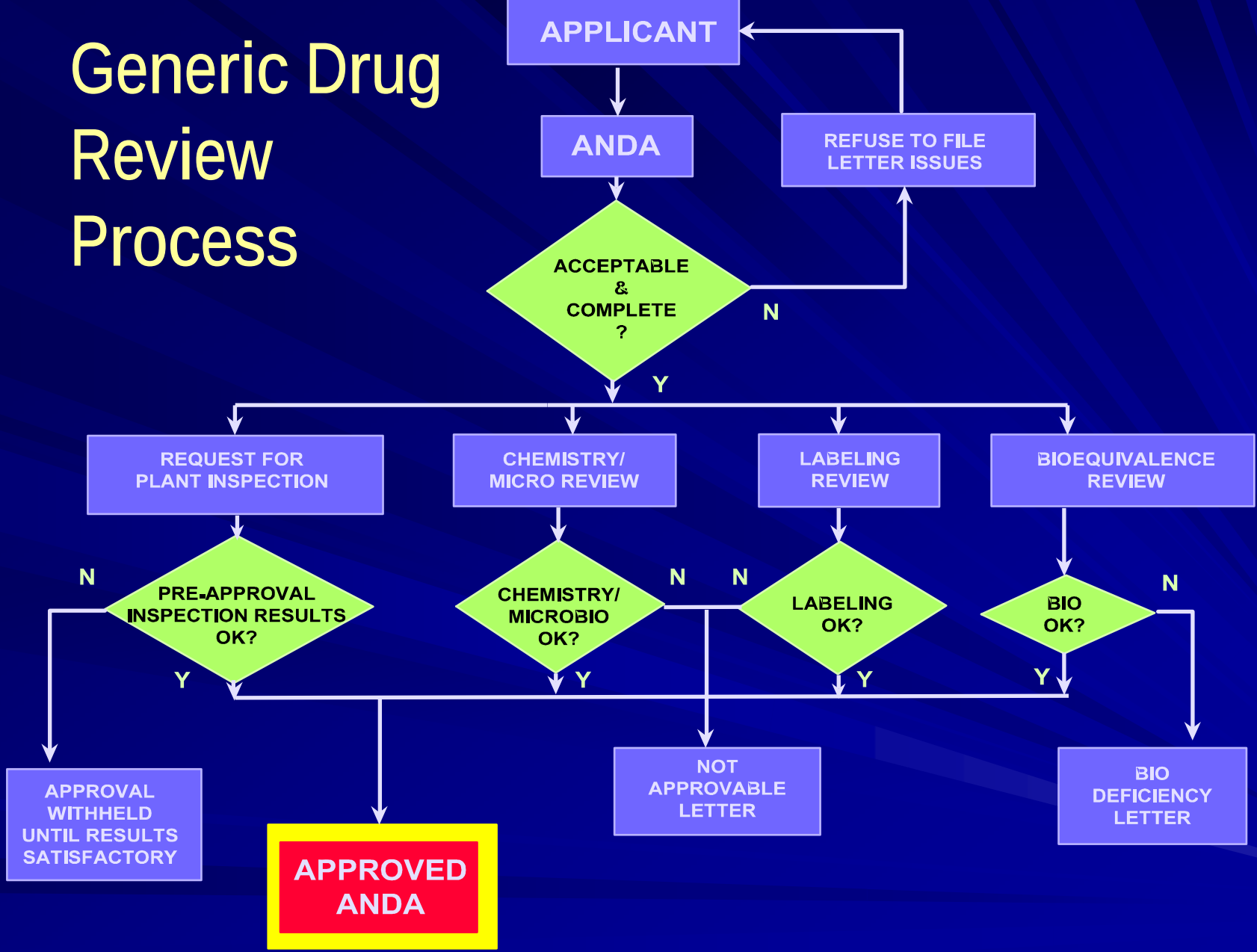
- Must be approved by stringent regulatory authority
- Must be proven safe and effective
- Requirements in place to avoid purchase of subpotent ARVs with PEPFAR dollars.
- Must be ‘registered’ in purchasing country where applicable

PEPFAR Goals (Focus Countries)

- Support treatment of 2 million HIV infected individuals
- Prevent 7 million new HIV infections
- Support care for 10 million people infected and affected by HIV/AIDs

The Office of Generic Drugs Approval Process and Contribution to PEPFAR.

Generic Drug Review Process



- Filing review is an initial quality control review of the submission.
- Request for inspection initiated now if information not previously submitted.
- OGD begins filing review of PEPFAR submissions approx. 2 days after receipt
- Once filed the ANDA immediately is expedited in the technical review queues

OGD Approval Timelines

PEPFAR

-Reviews are automatically expedited

-DMFs are reviewed in advance of ANDA submission when possible

-Filing review completed in 1 or 2 days

-All technical review disciplines begin reviews immediately

-Average time to Tentative approval is approximately 4 to 5 months

-Inspection of all facilities is expedited

Standard Approval

-Normally placed in regular review queue

-DMFs are reviewed in conjunction with ANDA review

-Filing review completed in 30 to 60 days

-Review of technical components is driven by the chemistry review. Goal for chem review is 180 days

-Average approval time for both TAs and Full Approvals is 17.8 months

-Inspections generally not expedited

PEPFAR Submission Requirements

- All applicants wishing to participate are eligible
- All granted expedited review
- May request pre-assignment of ANDA # to facilitate earlier inspection of facilities
- May submit less than full stability
- May submit less than all required BE studies
- Will not be TA’d until all review requirements are met

Patent Picture for Selected ARVs

- Lamivudine Tabs ‘082 expires 11/18/16
- Nevirapine Tabs ‘972 expires 5/22/12
- Efavirenz Caps ‘133 expires 4/6/19
- Stavudine Caps ‘655 expires 12/24/08
- Nevirapine Susp ‘972 expires 5/22/12
- Stavudine Soln ‘655 expires 12/24/08

Why not Faster?

- The original goal was to have ANDAs submitted under PEPFAR approved in 6 to 12 weeks
  - Can not issue TA until all required BE studies are found acceptable
  - Problems related to Finished drug product specifications
  - Scheduling of Inspections

What happens after TA?

- Difference in marketing requirements
  - Some countries require reapproval in the host country(MCC)
  - Some countries require WHO prequalification
  - Some countries accept FDA approval
- Tentatively Approved products are eligible for purchase with PEPFAR funds

OGD's Contributions

- 15 Tentatively Approved ARV's through December 2005
- Participated in Educational Workshop with focus countries in September 2005 with additional workshops anticipated
- Member of OGD have traveled to Africa to meet with peers in those countries.
- Members of OGD have met with representatives from several countries and from interested applicants to explain the process and provide guidance.

How is the PEPFAR program relevant to the Pharmacist Category?

- All filing reviews and labeling reviews conducted by Pharmacists.
- Pharmacist Project Managers in Chemistry and Bioequivalence ensure that reviews are conducted in a timely manner.
- Some BE reviews are conducted by Pharmacists.

Patent Related Issues

- PEPFAR submissions should be submitted containing Paragraph III certifications under 314.94(a)(12)(i)(A)(3)
- FDA will Tentatively Approve an ANDA that meets all scientific review requirements
- Product will not be eligible for marketing in the United States until Full Approval is granted

Additional Information/Useful Links

- Office of the Global AIDs Coordinator
  - http://www.state.gov/s/gac
- Office of Generic Drugs
  - www.fda.gov/cder/ogd/
- Second Annual Report to Congress
  - http://www.state.gov/s/gac/rl/c16742.htm

Questions or Comments????