FDA Public Meeting on The Prescription Drug User Fee Act

February 16, 2007

Alison Lawton

Senior Vice President, Regulatory Affairs and Corporate Quality Systems

Genzyme Corporation

BIO Supports the PDUFA IV Recommendations

- BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States.

- <u>BIO fully supports the PDUFA IV recommendations and urges swift enactment</u>

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PDUFA Has Been a Success

- Support for science driven, empirically based reviews of drugs and biologics
- Reduced review times and earlier patient access to needed therapies
- Consistent, multi-year funding source for long-term planning and program enhancements

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BIO Principles for Changes to Drug Safety Evaluation and Monitoring

- FDA Should Continue to Lead in Evaluating Safety and Efficacy
- Benefits and Risks Must be Considered Together
- Patients and Practitioners Benefit from Timely, Accurate, and Relevant Information
- Safety Systems Should Support and Reflect Innovation

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Enhanced Drug Safety Evaluation and Monitoring

- Modernized Approaches to Post-Market Surveillance
- Expediting Drug Development
- Improved Procedures to Ensure Timely and Valuable Pre-Market Reviews
- Reducing Medical Errors
- Information Technology Enhancements

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Significantly Enhanced Funding Base for PDUFA

- Resources to Facilitate the Efficient Review of New Drug and Biologic Applications

- Provides needed funding to address:
  - Inflationary pressures
  - Unanticipated workload volume and intensity
  - Facilities related costs

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PDUFA Cannot Succeed without Strong Appropriations

- Congress intended fees to be additive to FDA core appropriations
- Fees shoulder an increasing percentage of the cost of human drug review
- FDA requires increased appropriations to continue its mission
- Coalition for a Stronger FDA
  - Multi-Year Commitment to Strengthen FDA Appropriations
  - Industry groups, patient organizations, consumer advocates, and individual companies
  - www.fdacoalition.org

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Summary

- PDUFA III expires September 30th, 2007
- PDUFA Should Be Reauthorized in a Timely Manner
  - FDA is required to plan for a reduction in force by mid-summer
- PDUFA IV will enable FDA to enhance & modernize drug safety systems

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