Use of Risk-based Approach for Regulating CMC Changes to Approved Applications

FDA Public Meeting

February 7, 2007

Genentech Supports Proposed Revisions to 314.70

- Implements objectives of FDA 21st Century Pharmaceutical CGMP Initiative
- Embraces global quality initiatives defined in ICH Q8, Q9 and Q10
- Facilitates manufacturing process innovations and improvements
- Allows for more rapid and predictable release of life saving medicines

Genentech Concerns about Proposed Revisions to 314.70

- FDA should revise both 314.70 and 601.12
  - FR notice only addresses revisions to 314.70
  - Many natural and recombinant DNA-derived products regulated under 314.70
  - No scientific and technical reason that biotech products regulated under 601.12 should be treated differently
  - April 8, 2004 final rule on changes to approved applications applied to drugs and biologics
  - Ensure consistency in handling manufacturing changes for specified biotech products

Genentech Concerns about Proposed Revisions to 314.70

- Need effective team work between CMC reviewer and Field Investigator
  - Clear communication
  - Uniform expectations
  - Shared understanding of regulatory agreements
- Harmonize respective variation regulations with other international regulatory agencies