MANAGEMENT CHALLENGES FOR FY 2013

To meet the demanding review time goals established under AGDUFA in FY 2013, FDA will be challenged to:

- Work with stakeholders and Congress to support the reauthorization of AGDUFA while at the same time striving to meet challenging performance goals with reduced time frames.
- Respond to many more new submissions that industry advises us to expect while continuing to meet the performance goals.
- Operate with a great deal of fiscal uncertainty as the new fiscal year begins, including working with a six month continuing resolution.
- Not knowing whether there will be an appropriation reduction, and, if so, to what extent and how that would impact the program.
- Continue to implement a process allowing for sponsors to amend similar submissions pending in the queue when the agency requests an amendment to a certain submission type.
- Maintain staffing necessary to help FDA meet AGDUFA review time goals.

FDA is committed to improving the efficiency, quality, and predictability of the generic new animal drug review process. We are dedicated to exploring new approaches and technologies that offer high quality and cost-effective improvements in FDA's review of Abbreviated New Animal Drug Applications (ANADAs) and other submissions. FDA looks forward to significant improvements in the generic new animal drug review process that AGDUFA helps make achievable.