Animal Generic Drug User Fees
+ $4,831,000 / 22 FTE

1. Why is this funding necessary?

The funds in this initiative are new user fees that support the review of Abbreviated New Animal Drug Applications (ANADA), also known as generic animal drug applications. The new user fees will provide essential resources to reduce the amount of time to review generic animal drug applications.

The volume of generic animal drug applications relative to the resources for this program has resulted in a significant increase in review times. For example, the review time for ANADA (original applications and reactivations of applications) increased from 380 days in FY 2003 to 570 days in FY 2007. Moreover, since FY 2003, the backlog of generic animal drug submissions increased five-fold.

2. What activities will these funds support?

The funds will support the following activities:

- improving application review efficiency and instituting business process improvements to enhance the process for managing applications
- incrementally decreased review times for generic animal drug applications
- maintaining high standards for product safety and efficacy.

FDA will also ensure that generic animal drugs conform to good manufacturing practices and controls to assure product purity, strength, and safety.

3. What are the risks of not funding this initiative?

Not proceeding with this initiative will mean an inability to capture the savings that result from generic animal drug use. Another risk is the potential for increased use of alternative therapeutic options, including counterfeit and illegally compounded animal drugs. Compounded animal drug products are not manufactured according to current Good Manufacturing Practice (cGMP) standards. These products also lack proof of safety and effectiveness, particularly safety for the human food products derived from animals treated with these products.

4. How does this initiative support important public health priorities?

This initiative supports the President's vision for transforming healthcare for the 21st century. The initiative also supports the Department of Health and Human Services priority to transform health through improved regulatory processes that safely make new drugs and other medical products available in less time.

5. What results will FDA achieve?

FDA will work with stakeholders to establish review performance goals phased in over a five-year period (FY 2009 – FY 2013). The program performance goals will lead to progressive, yearly performance improvements, with the time for review and action on submissions getting shorter each fiscal year. By the fifth and final year of the proposed user fee program, FDA would agree to review and act on the following submission types within specified times:

1. Review and act on 90 percent of non-administrative original ANADAs and reactivations of ANADAs within 270 days of the submission date.
2. Review and act on 90 percent of manufacturing supplemental ANADAs and reactivations of supplemental ANADAs within 270 days after submission date.
3. Review and act on 90 percent of generic investigational new animal drug (JINAD) study submissions within 270 days after submission date.
4. Review and act on 90 percent of JINAD submissions consisting of protocols without substantial data that FDA and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an ANADA or supplemental ANADA without substantial data, within 100 days after submission date.
5. Review and act on 90 percent of administrative ANADAs (ANADAs submitted after all scientific decisions have been made in the JINAD process, i.e., prior to the submission of the ANADA) within 100 days after the submission date.