-IMPORTANT INFORMATION-

PASSAGE OF THE ANIMAL DRUG USER FEE ACT OF 2003

On November 18, 2003 the President signed the Animal Drug User Fee Act of 2003 (ADUFA). The Act authorizes FDA to collect user fees for certain types of animal drug applications, establishments where those products are made, on such products, and sponsors of those applications or investigational applications submitted on or after September 1, 2003.

Before FDA can begin collecting fees, Congress must also pass an appropriation act providing for the new animal drug fees and FDA must develop systems to collect, safeguard, process, and account for fees. FDA is not canceling any submissions and is not asking applicants to withdraw any submissions due to lack of fee payment during this transition period. Review activities will continue as usual for all submissions made on or after September 1, 2003.

Until such time that we can publish detailed payment instructions and provide FY 2004 Fee Rates, we ask that you **do not send any fee payments** to FDA. Upon completion of these detailed payment procedures and the enactment of FY 2004 enabling appropriations for ADUFA user fees, FDA will publish a *Federal Register* announcement so notifying you of such procedures including the FY 2004 Fee Rates.

Do not send payment for fees owed until FDA 1) publishes a Federal Register notice providing detailed payment instructions along with the FY 2004 Fee Rates, and, 2) invoices you for any fee owed.

How to obtain additional information on the requirements of the new law?

Basic information concerning ADUFA is available at http://www.fda.gov/cvm/index/adufa/adufa.htm . The information on this site will be updated and expanded and should provide the latest information and guidance from FDA concerning the implementation of the new law. For additional general information or questions regarding ADUFA, please contact the Center for Veterinary Medicine at (mailto:cvmadufa@fda.gov).