

Animal Generic Drug User Fee Signed into Law

Fees generated under a new law will be dedicated toward improving generic animal drug review time.

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President Bush signs a bill that would make animal drugs more affordable and available to American pet owners. President Bush signed into law the Animal Drug User Fee Amendments of 2008 (H.R. 6432) on Thursday, which among other things, authorizes a new user fee program for animal generic drugs.

Under the Animal Generic Drug User Fee Act of 2008, animal health companies will have to pay user fees based on three categories: 1) application fees, 2) generic new animal drug product fees and 3) generic new animal drug sponsor fees.

These funds — estimated to bring in about \$27 million over five years — would in turn be dedicated toward expediting the development process and the review of applications for new generic animal health drugs.

“According to the FDA, the average review time of an animal generic drug submission was 570 days in fiscal year 2007, in spite of a 180 day statutory requirement,” sponsor U.S. Rep. Frank Pallone Jr. [D-N.J.] said in a statement. “At the end of last year, there was a recorded backlog of 446 submissions waiting for review and agency action. ... By year five of the authorization period, most reviews of generic animal drug submissions should occur in 270 days or less, a substantial improvement over the time it is now taking FDA to conduct such reviews.”

Congress said that prompt approval of these applications will reduce animal health care costs and promote the well-being of animal health and public health.

“The [Animal Generic Drug User Fee] legislation marks the beginning of a new era for animal health,” said Jean Hoffman, chief executive of Putney, which is a member of the trade organization Generic Animal Drug Alliance. “Much as generics have changed the face of human health care — making drugs more affordable for Americans — the timely availability of animal generics will help ranchers and farmers manage the cost of caring for our country’s food and production animals, and allow pet owners access to lower cost medications for their companion animals who are considered members of the family.”

In addition, H.R. 6432 reauthorizes the Animal Drug User Fee Act through fiscal year 2013.

This increases the amount of fees collected for the review of animal drug submissions from \$15 million to \$24 million over five years for a total of about \$98 million. Revenue would come from application, product, establishment and sponsor fees.