LEGISLATIVE DIGEST
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H.R. 6432 – Animal Drug User Fee Amendments of 2008

FLOOR SITUATION

H.R. 6432 is being considered on the floor under suspension of the rules and will require a two-thirds majority vote for passage. This legislation was introduced by Representative Frank Pallone (D-NJ) on July 8, 2008. The bill was ordered reported as amended from the Committee on Energy and Commerce, by voice vote, on July 16, 2008.

H.R. 6432 is expected to be considered on the floor of the House on July 30, 2008.

SUMMARY

Animal Drug User Fee Amendments (ADUFA): The bill reauthorizes the FDA's ability to assess and use animal drug fees. The total fee revenues for application, supplement, and product fees for fiscal years 2009 through 2013 are specified in the bill. The bill authorizes $15.2 million for 2009, $17.3 million for 2010, $19.4 million for 2011, $21.7 million for 2012, and $24.2 million for 2013. H.R. 6432 stipulates that if the amount of fees collected from 2009 to 2011 exceeds the appropriated amount, the excess funds will be credited to the FDA appropriation account and will be subtracted from the fees that would be authorized for collection in 2013.

According to H.R. 6432, the Secretary must report annually to Congress on the FDA's progress toward achieving the goals of this Act. The Secretary must also report on the implementation of the fee authority, and the fees collected during each fiscal year. The Secretary must publish these reports on the FDA website. This bill establishes a number of criteria the Secretary must fulfill before developing recommendations to present to Congress regarding the review of animal drug applications. These requirements include consultation with veterinarians, Congress, and industry representatives.

Each sponsor of a new animal drug that contains an antimicrobial active ingredient must report to the Secretary annually on the amount of each antimicrobial active ingredient that is sold or distributed for use in food-producing animals. The Secretary must make summaries of these reports publicly available, while ensuring protection of national security and confidential business information.

The authorizations described above take effect October 1, 2008. This authorization will sunset on October 1, 2013. The reporting requirements in this bill will sunset January 31, 2014.

Animal Generic Drug User Fee (AGDUFA): The bill gives the Secretary new authority to assess and use fees for generic new animal drugs. The total fee revenues for application, sponsor, and product fees for fiscal year 2009 through 2013 are specified in the bill. H.R. 6432 authorizes $4.831 million for 2009, $5.106 billion for fiscal year 2010, $5.397 million for fiscal year 2011, $5.706 million for fiscal year 2012, and $6.031 million for fiscal year 2013. H.R. 6432 stipulates that if the amount of fees collected from 2009 to 2011 exceeds the appropriated amount, the excess funds will be credited to the FDA appropriation account and will be subtracted from the fees that would be authorized for collection in 2013.

The bill requires the FDA to provide Congress with annual reports on the performance and progress of expediting the generic new animal drug development process and annual reports on the amount of fees collected and used by the FDA. In addition, the FDA is required to consult with Congress, scientific and academic experts, veterinary professionals, advocacy groups and the regulated industry prior to making a recommendation for the reauthorization of the bill in 2013.

The authorizations described above take effect October 1, 2008. This authorization will sunset on October 1, 2013. The reporting requirements in this bill will sunset January 31, 2014.

BACKGROUND

The Animal Drug User Fee Act of 2003 (ADUFA I, P.L. 108-130) provided the Food and Drug Administration with the authority to collect user fees from the animal drug industry for the review of drug applications, similar to the user fee programs used for human drugs and medical devices. According to the FDA, the supplemental funds provided by ADUFA user fees have enabled the review times for new animal drug applications to decrease from 295 days to 180 days because they have been able to hire additional staff, provide educational and training opportunities to animal drug reviewers, developed guidance, policy, and procedural documents, and implemented improvements to their business process. Authorization for ADUFA expires on October 1, 2008.

Generic animal drugs are currently funded through Congressional appropriations. According to the FDA, there was a backlog of 446 submissions for generic animal drugs and the review time for these drugs averaged 570 days (by law FDA is supposed to review these applications within 180 days).

> **Note: ADUFA and AGDUFA were initially stand alone bills (H.R. 6432 and H.R. 6433, respectively), but have been integrated.*

COST

According to the Congressional Budget Office, "CBO estimates that implementing H.R. 6432 would reduce discretionary outlays, on net, by $6 million over the 2009-2013 period, assuming the necessary authorities are provided in appropriation acts. The bill would not affect direct spending or revenues." (CBO Cost Estimate)

According to the Congressional Budget Office cost estimate for H.R. 6433 (AGDUFA), "CBO estimates that implementing H.R. 6433 would reduce discretionary outlays, on net, by $1 million over the 2009-2013 period, assuming the necessary authorities are provided in appropriation acts. Enacting the bill would not affect direct spending or revenues." (CBO Cost Estimate)

STAFF CONTACT

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