CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

July 28, 2008

H.R. 6432
Animal Drug User Fee Amendments of 2008

As ordered reported by the House Committee on Energy and Commerce
on July 16, 2008

SUMMARY

H.R. 6432 would authorize the collection and spending of user fees by the Food and Drug Administration (FDA) for certain activities to expedite the development and marketing approval of drugs for use in animals. Fees would supplement appropriated funds to cover FDA's cost associated with reviewing certain applications and investigational submissions for animal drugs. Such fees could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. The legislation would extend through fiscal year 2013 and make several technical changes to the existing user fee program for animal drugs, which expires at the end of fiscal year 2008.

H.R. 6432 would also require sponsors of new animal drugs to submit annual reports to FDA on certain products that contain antimicrobial active ingredients, and it would require FDA to make summaries of such information publicly available.

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.

H.R. 6432 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA).

The bill would impose private-sector mandates, as defined in UMRA, because it would require manufacturers of drugs for use in animals to pay specified fees to FDA and to submit reports to the agency for certain products. CBO estimates that the direct cost of complying with these requirements would not exceed the annual threshold established by UMRA for private-sector mandates ($136 million in 2008, adjusted annually for inflation).

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 6432 is shown in the following table. The costs of this legislation fall primarily within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					
	2009	2010	2011	2012	2013	2009-2013
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Food and Drug Administration (FDA)						
Collection of User Fees						
Estimated Authorization Level	-15	-17	-19	-22	-27	-101
Estimated Outlays	-15	-17	-19	-22	-27	-101
Spending of User Fees						
Estimated Authorization Level	15	17	19	22	27	101
Estimated Outlays	11	17	19	22	24	93
Administrative Expenses						
Estimated Authorization Level	1	*	*	*	*	2
Estimated Outlays	1	*	*	*	*	2
Net Effect on Spending by FDA						
Estimated Authorization Level	1	*	*	*	*	2
Estimated Outlays	-3	*	*	*	-3	-6

Note: * = between -$500,000 and $500,000. Components may not sum to totals because of rounding.

BASIS OF ESTIMATE

For this estimate, CBO assumes that H.R. 6432 will be enacted near the start of fiscal year 2009, that the full amounts authorized will be collected and appropriated for each year, and that outlays will follow historical patterns for the program. Assuming appropriation action consistent with the bill, CBO estimates that implementing H.R. 6432 would reduce discretionary outlays, on net, by $6 million over the 2009-2013 period, primarily because the spending of authorized fees lags slightly behind their collection.

User Fees for Animal Drugs

H.R. 6432 would authorize FDA to assess and collect certain fees from manufacturers of drugs for use in animals to help defray FDA's costs of expediting the regulatory review process for such drugs. Under current law, the user fee program for animal drugs will expire at the end of fiscal year 2008.

Similar to the existing fee structure, four categories of user fees would be authorized by the bill: (1) animal drug application and supplement fees, (2) animal drug product fees, (3) animal drug establishment fees, and (4) animal drug sponsor fees. The bill would authorize the appropriation of specific aggregate amounts of collections for each fiscal year 2009 through 2013. Collections could be modified each year based on certain workload estimates, when applicable. The legislation also would make several technical changes to the existing user fee program.

Fees authorized by H.R. 6432 could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. CBO estimates that FDA would assess and collect the amounts specified in the bill without any additional adjustment for workload. (No such adjustments have occurred over the last 5 years of the existing program and we expect that they would not occur in the future.) For fiscal year 2013, the bill would authorize the assessment and collection of up to three months of operating reserves for the first three months of fiscal year 2014. In total, we estimate aggregate collections from fees authorized by the bill would amount to $101 million over the 2009-2013 period.

The legislation would retain the existing statutory limitation that user fees cannot be assessed in a given year unless appropriations for salaries and expenses of FDA (excluding the amount of user fees appropriated for such fiscal year) in that year satisfy a maintenance-of-effort requirement. The fees could be assessed if the amount appropriated exceeded the amount appropriated for 2003 increased by an adjustment factor that reflects the percentage increase in the consumer price index for all urban consumers. In addition, fees could be collected and made available to defray increases in the cost of resources allocated to reviewing animal drug applications only to the extent that the percentage increase in those costs (excluding fees) exceeds the costs for fiscal year 2003 adjusted by the adjustment factor. This estimate assumes that such conditions would be met.

Before accounting for costs associated with additional administrative activities not covered by the user fees and other activities required by the bill, CBO estimates that authorizing the user fee program for the 2009-2013 period would reduce discretionary outlays, on net, by $8 million over the 2009-2013 period, assuming appropriation action consistent with the bill.

The estimated authorization levels for collections and spending offset each other exactly from 2009 through 2013. However, spending of authorized fees lags somewhat behind their collection thereby generating savings over the period. In addition, amounts available for obligation and spending for fiscal year 2013 would not include additional special reserve funds collected in that year. CBO estimates that difference would result in savings of $3 million for fiscal year 2013.

Other Administrative Expenses

Funding for certain administrative activities associated with the new user fee program would not be fully covered by fees. The bill would require that FDA report annually to the Congress on its performance under the user fee program and on the fiscal status of the program. H.R. 6432 would require that FDA consult with the Congressional committees of jurisdiction and outside experts, including industry and consumer groups, and publish its recommendations concerning reauthorization of the user fee program on a specified schedule. In addition, H.R 6432 would also require sponsors of animal drugs to submit annual reports to FDA on certain new products that contain antimicrobial active ingredients, and it would require FDA to make summaries of such information publicly available. CBO estimates that the administrative activities associated with implementing the user fee program that are not covered by the user fees and other activities required by the bill would cost between $1 million and $2 million over the 2009-2013 period.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

H.R. 6432 contains no intergovernmental mandates as defined in UMRA.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

H.R. 6432 would require sponsors of drugs intended for use in animals to pay application, product, establishment, and other related fees to FDA. The bill also would require sponsors of new animal drugs containing active antimicrobial ingredients to submit an annual report to FDA regarding the amount of these ingredients and additional information specified by the bill.

Both of these requirements would be considered private-sector mandates as defined in UMRA. CBO estimates that the fees collected over the 2009-2013 period would total $101 million. CBO also estimates that the direct cost of complying with both of these requirements would not exceed the annual threshold specified in UMRA ($136 million in

2008, adjusted annually for inflation) in any of the five years that the mandates would be effective.

ESTIMATE PREPARED BY:

Federal Costs: Julia Christensen
Impact on State, Local, and Tribal Governments: Lisa Ramirez-Branum
Impact on the Private Sector: Paul Jacobs

ESTIMATE APPROVED BY:

Keith J. Fontenot
Deputy Assistant Director for Health and Human Resources,
Budget Analysis Division