CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

July 28, 2008

H.R. 6433
Animal Generic Drug User Fee Act of 2008

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

SUMMARY

H.R. 6433 would amend the Federal Food, Drug, and Cosmetic Act to authorize the Food and Drug Administration (FDA) to collect fees to cover the cost for certain activities to expedite the development and marketing of generic new drugs for use in animals. Fees would supplement appropriated funds to cover FDA's cost associated with reviewing certain marketing applications and investigational submissions for such drugs. Those fees 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 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.

H.R. 6433 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA).

The bill's requirement that sponsors of generic new drugs for use in animals to pay certain fees to FDA would be a private-sector mandate as defined in UMRA. However, CBO estimates that the direct cost of complying with this requirement would not exceed the annual thresholds 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. 6433 is shown in the following table. The costs of this legislation fall 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	-5	-5	-5	-6	-8	-29
Estimated Outlays	-5	-5	-5	-6	-8	-29
Spending of User Fees						
Estimated Authorization Level	5	5	5	6	8	29
Estimated Outlays	3	6	6	6	6	27
Administrative Expenses						
Estimated Authorization Level	*	*	*	*	*	1
Estimated Outlays	*	*	*	*	*	1
Net Effect on Spending by FDA						
Estimated Authorization Level	*	*	*	*	*	1
Estimated Outlays	-2	1	*	*	-1	-1

Note: * = less than $500,000. Components may not sum to totals because of rounding.

BASIS OF ESTIMATE

For this estimate, CBO assumes that H.R. 6433 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 similar activities. Assuming appropriation action consistent with the bill, CBO estimates that implementing H.R. 6433 would reduce discretionary outlays, on net, by $1 million over the 2009-2013 period, primarily because the spending of authorized fees slightly lags behind their collection.

User Fees for Generic New Drugs for Use in Animals

H.R. 6433 would establish a new user fee program to help defray FDA's costs of expediting and improving the regulatory review process for generic new drugs for use in animals. It would require FDA to assess and collect application and other user fees from manufacturers of generic new drugs for use in animals to expedite the development of such drugs and the review of new and supplemental abbreviated applications and investigational submissions for such products.

The bill would create three categories of user fees: (1) abbreviated application fees, (2) fees on generic new drug products for animals, and (3) fees on sponsors of generic new drugs for animals. The aggregate amounts of such fees are specified for each of fiscal years 2009 through 2013. Each year, the amounts to be collected could be adjusted further for workload estimates, when applicable. For fiscal year 2013, the bill also would authorize the assessment and collection of up to three months of operating reserves for the first three months of fiscal year 2014.

Fees authorized by H.R. 6433 could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. In total, we estimate that aggregate collections from fees authorized by the bill would amount to $29 million over the 2009-2013 period, assuming the necessary appropriation action.

Under the bill, user fees could not 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 user 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 abbreviated applications for generic new drugs for use in animals 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, CBO estimates that establishing the user fee program would reduce discretionary outlays, on net, by $2 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 net savings over the period. In addition, the amounts available for obligation and spending for

fiscal year 2013 would not include special reserve funds collected in that year. That difference would result in savings of almost $2 million for fiscal year 2013, CBO estimates.

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. 6433 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. CBO estimates that the administrative activities associated with implementing the user fee program that are not covered by the user fees would cost less than $500,000 annually.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

H.R. 6433 contains no intergovernmental mandates as defined in UMRA.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

H.R. 6433 would establish a user fee program at FDA for sponsors of generic drugs intended for use in animals. The imposition of application, product, and sponsor fees that private entities would pay to FDA would be considered a private-sector mandate as defined in UMRA. CBO estimates that the fees collected over the 2009-2013 period would total $29 million. Those amounts 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.

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