CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

March 20, 2013

S. 622
Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013

As reported by the Senate Committee on Health, Education, Labor, and Pensions on March 20, 2013

SUMMARY

S. 622 would authorize the collection and spending of 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 costs associated with reviewing certain applications and investigational submissions for brand and generic 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 2018, and make several technical changes to, FDA's existing fee programs for brand and generic animal drugs, which expire at the end of fiscal year 2013.

CBO estimates that implementing S. 622 would reduce discretionary outlays, on net, by $7 million over the 2014-2018 period, assuming appropriation actions consistent with the bill.

Pay-as-you-go procedures do not apply to this legislation because it would not affect direct spending or revenues.

S. 622 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. CBO estimates that the direct cost of complying with these requirements would not exceed the annual threshold established by UMRA for private-sector mandates ($148 million in 2014, adjusted annually for inflation).

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of S. 622 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					
	2014	2015	2016	2017	2018	2014-2018
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Title I: Fees Relating to Animal Drugs						
Collections from Fees						
Estimated Authorization Level	-24	-22	-22	-23	-23	-114
Estimated Outlays	-24	-22	-22	-23	-23	-114
Spending of Fees						
Estimated Authorization Level	24	22	22	23	23	114
Estimated Outlays	19	21	22	23	23	109
Subtotal, Estimated Authorization Level	0	0	0	0	0	0
Subtotal, Estimated Outlays	-5	-1	*	*	*	-6
Title II: Fees Relating to Generic Animal Drugs						
Collections from Fees						
Estimated Authorization Level	-7	-7	-7	-8	-8	-38
Estimated Outlays	-7	-7	-7	-8	-8	-38
Spending of Fees						
Estimated Authorization Level	7	7	7	8	8	38
Estimated Outlays	6	7	7	8	8	36
Subtotal, Estimated Authorization Level	0	0	0	0	0	0
Subtotal, Estimated Outlays	-1	*	*	*	*	-2
Administrative Expenses						
Estimated Authorization Level	*	*	*	*	*	1
Estimated Outlays	*	*	*	*	*	1
Net Effect on Spending by the Food and Drug Administration						
Estimated Authorization Level	*	*	*	*	*	1
Estimated Outlays	-6	-1	*	*	*	-7

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

BASIS OF ESTIMATE

For this estimate, CBO assumes that S. 622 will be enacted near the start of fiscal year 2014, that the full amounts authorized will be collected and appropriated for each year, and that outlays will follow historical patterns for the fee programs. Assuming appropriation actions that trigger the collection of fees and are consistent with other provisions of the bill, CBO estimates that implementing S. 622 would reduce discretionary outlays, on net, by $7 million over the 2014-2018 period, mostly because the spending of authorized fees lags slightly behind their collection.

Conditions for Assessment and Use of Fees

S. 622 would authorize the collection and spending of fees by FDA for certain activities to expedite the development and marketing approval of drugs for use in animals for fiscal years 2014 through 2018. Under current law, FDA administers two separate fee programs involving animal drugs: One program covers brand-name animal drugs and the other program covers generic drugs for use in animals. Both fee programs will expire at the end of fiscal year 2013.

Fees authorized by the bill could be collected and made available for obligation by FDA only to the extent and in the amounts provided in advance in appropriation acts. The legislation would also retain the existing statutory limitations that 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) satisfy a maintenance-of-effort requirement. Fees could be assessed only if the amount appropriated in that year equals or exceeds 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, for each of the programs, fees could be collected and spent in a given year only if the cost of resources allocated to reviewing brand and generic animal drug applications (excluding fees) exceeds the amount that is 3 percent below the level allocated for such activities in a base year inflated by an adjustment factor. This estimate assumes that such conditions would be met.

Title I: Fees Relating to Animal Drugs

S. 622 would authorize FDA to assess and spend certain fees from manufacturers of brand-name drugs for use in animals to help defray FDA’s costs of expediting the regulatory review process for such drugs through fiscal year 2018. For fiscal year 2012, FDA collected about $21 million in fees associated with brand-name animal drugs.

Similar to the existing fee structure, four categories of fees would be authorized by title I of 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. S. 622 would authorize the appropriation of specific aggregate amounts of collections for each fiscal year 2014 through 2018, subject to further adjustments defined by the legislation. Collections would be adjusted each year by an inflation factor to reflect changes in FDA's operating costs. Collections could also be modified based on certain workload estimates, when applicable. (No such adjustments for workload have occurred over the last four years of the existing program, and we expect that they would not occur in the future.) For fiscal year 2018, the bill would authorize the collection of operating reserves for the beginning of fiscal year 2019, unless carryover balances for the fee program exceed three months of such reserves. CBO expects that the final-year adjustment for operating reserves would not be made. We estimate aggregate collections from fees for the brand animal drug program authorized by S. 622 would total $114 million over the 2014-2018 period.

CBO estimates that authorizing the fee program for brand animal drugs through 2018 would reduce discretionary outlays, on net, by $6 million over the 2014-2018 period, assuming appropriation actions consistent with the bill. The estimated authorization levels for collections and spending offset each other exactly from 2014 through 2018. However, spending of authorized fees lags somewhat behind their collection, thereby generating savings over the period.

Title II: Fees Relating to Generic Animal Drugs

S. 622 would extend FDA's authority to assess and spend fees from manufacturers of certain generic new drugs for use in animals that would help cover the costs of regulatory activities to expedite the development and approval for marketing such drugs through fiscal year 2018. (The term "generic new drug" refers to drugs that must gain marketing approval by FDA because they are not generally recognized as safe and effective for use in animals and are approved under an abbreviated review process.) Collections associated with FDA's fee program for generic animal drugs totaled about $7 million for fiscal year 2012.

Three categories of fees would be authorized by title II of the bill: (1) fees for abbreviated applications, (2) fees on generic new drug products for animals, and (3) fees on sponsors of generic new drugs for animals. The bill would authorize the appropriation of specific aggregate amounts of collections for each fiscal year 2014 through 2018. Collections could be further adjusted each year based on certain workload estimates, when applicable. (No such adjustments for workload have occurred over the last four years of the existing program, and we expect that they would not occur in the future.) For fiscal year 2018, the bill would authorize additional adjustments to collections under specific circumstances, including the assessment of up to three months of operating reserves for the beginning of

fiscal year 2019, unless carryover balances for the fee program exceed three months of such reserves. CBO expects that the final-year adjustment for operating reserves would not be made. We estimate aggregate collections from fees for generic new animal drugs authorized by the bill would total $38 million over the 2014-2018 period.

CBO estimates that authorizing the fee program for generic new animal drugs over the 2014-2018 period would reduce discretionary outlays, on net, by $2 million over that period, assuming appropriation actions consistent with the bill. Because FDA would have the authority to spend collections, the estimated negative budget authority resulting from collections would exactly offset the budget authority for spending in each fiscal year. However, spending of fees would lag behind the collections and thus generate net discretionary savings over the 2014-2018 period.

Other Administrative Expenses

Funding for certain administrative activities associated with the fee programs authorized by S. 622 would not be fully covered by fees. The bill would require that FDA report annually to the Congress on its performance under the fee programs and on the fiscal status of the programs. The legislation would also 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 fee programs. CBO estimates that such administrative activities associated with implementing S. 622 that are not covered by fees would cost less than $500,000 annually.

PAY-AS-YOU-GO CONSIDERATIONS: None.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

S. 622 contains no intergovernmental mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

The imposition of application, product, establishment, 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 2014-2018 period would total $153 million. Those amounts would not exceed the annual threshold specified in UMRA ($148 million in 2014, adjusted annually for inflation) in any of the five years that the mandate would be effective.

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