# CONGRESSIONAL BUDGET OFFICE
# COST ESTIMATE

July 1, 2004

# S. 741

## An act to amend the Federal Food, Drug, and Cosmetic Act with regard to new animal drugs, and for other purposes

*As passed by the Senate on March 8, 2004*

## SUMMARY

S. 741 aims to increase the market availability of new animal drugs for minor species and for minor uses in major species of animals. It would amend the Federal Food, Drug, and Cosmetic Act (FFDCA) to authorize the Food and Drug Administration (FDA) to establish a conditional approval process for such drugs and to create an index of legally marketed unapproved drugs to treat certain minor species. It also would authorize grants to help defray a portion of the cost associated with the development of designated drugs and would award seven years of marketing exclusivity to products meeting certain criteria.

S. 741 also would require that labels for food products indicate in plain English the presence of any of the eight major food allergens, and would direct the Secretary of Health and Human Services to engage in a number of activities to increase scientific and public understanding of issues related to food allergies.

CBO estimates that implementing S. 741 would cost $6 million in 2005 and $60 million over the 2005-2009 period, assuming appropriation of the necessary funds.

The legislation would not affect direct spending. There would be potential for higher revenues through penalties imposed on sponsors of misbranded or illegally marketed drugs or of mislabeled food products. However, the FDA generally issues warning letters to violators and works with them to correct the violation. For chronic violators or for serious offenses, the FDA generally pursues injunctions or seizes products; prosecution, which can involve penalties, generally is a last resort. Therefore, CBO expects that revenues from such penalties would be negligible.

S. 741 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). The act's provisions would increase the availability and broaden the potential uses of certain drugs used to treat minor species animals and also to treat minor

conditions in major species. State and local conservation programs, zoos, and animal shelters could take advantage of those new drugs or uses, and the impact on their budgets would likely be positive.

The act would impose a private-sector mandate on the manufacturers, packagers, and labelers of processed foods by requiring them to display on the label the names of the major food allergens from which the ingredients are derived. The act also would impose mandates on some manufacturers of generic animal drugs for minor uses or use in minor species by potentially delaying the time at which their products could enter the market. CBO estimates that the direct cost of these mandates would not exceed the threshold established by UMRA ($120 million in 2004, adjusted annually for inflation) in any of the first five years the mandates would be effective.

## ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of S. 741 is shown in the following table. The costs of this act fall within budget function 550 (health).

| | By Fiscal Year, in Millions of Dollars | | | | |
|---|---|---|---|---|---|
| | 2005 | 2006 | 2007 | 2008 | 2009 |
| **CHANGES IN SPENDING SUBJECT TO APPROPRIATION** | | | | | |
| Title I: Minor Use and Minor Species Animal Health Act of 2004 | | | | | |
| Estimated Authorization Level | 1 | 1 | 2 | 3 | 4 |
| Estimated Outlays | 1 | 1 | 2 | 3 | 3 |
| Title II: Food Allergen Labeling and Consumer Protection Act of 2004 | | | | | |
| Estimated Authorization Level | 12 | 12 | 12 | 12 | 12 |
| Estimated Outlays | 5 | 10 | 11 | 12 | 12 |
| Net Effect on Spending by the Food and Drug Administration[a] | | | | | |
| Estimated Authorization Level | 13 | 13 | 14 | 15 | 16 |
| Estimated Outlays | 6 | 11 | 13 | 15 | 15 |

a. CBO assumes that a portion of the costs associated with the conditional approval process proposed under S. 741 would be covered by user fees collected from sponsors seeking approval to market animal drugs. (User fees are collected and made available for obligation only to the extent, and in the amount, provided in advance in appropriation acts.) We estimate that additional collections associated with activities required by the act would total less than $500,000 annually.

## BASIS OF ESTIMATE

For this estimate, CBO assumes that S. 741 will be enacted this fall and that the amounts necessary to implement the bill will be appropriated for each year.

### Spending Subject to Appropriation

S. 741 would increase the availability of approved or legally marketed animal drugs for minor species and for minor uses in major species and would modify food labeling requirements regarding food allergens. CBO estimates that implementing the act would cost the FDA $6 million in 2005 and $60 million over the 2005-2009 period, subject to the availability of appropriated funds.

**Title I: Minor Use and Minor Species Animal Health Act of 2004.** S. 741 would create two procedures within the FDA to allow sponsors to lawfully market animal drugs without final approval for use in minor species and for minor uses in major species. (Minor species are species other than cattle, horses, swine, chickens, turkey, dogs, and cats. A minor use in a major species refers to the intended use of a drug in a major species for a disease that occurs in a small number of animals and occurs either infrequently or in limited geographic areas.) The act also would authorize grants and award market exclusivity to encourage the development of new drugs for animals, and it would establish a new office within the FDA to administer activities related to regulating animal drugs for minor uses and minor species.

*New procedures for legal marketing of animal drugs.* Under current law, the FDA will approve drugs for marketing only after the sponsor has demonstrated that the drug is both safe and effective. The act would require the Secretary of the Health and Human Services to establish a process for granting conditional approval of new animal drugs intended for minor uses and for use in minor species. Conditional approval would be granted for one year at a time, and could be renewed for a total of five years.

S. 741 also would require the Secretary to establish a process for listing on an index unapproved drugs that may be marketed legally for use in certain minor species. Eligibility for listing on the index would apply to drugs for animals that are not consumed by humans or food-producing animals, or for use in a non-food life stage of a minor species (such as the larval form of shellfish) in a contained man-made structure (such as a hatchery pond or tank). The Secretary could place a drug on the index if the sponsor demonstrates that the drug meets certain safety criteria and if an expert panel concludes that the benefits of using the drug outweigh its risks to the target animal.

Based on information from the FDA, CBO anticipates that the cost to the FDA associated with implementing those procedures to allow sponsors to lawfully market animal drugs without final approval would total less than $500,000 annually. CBO assumes a portion of the costs associated with the conditional approval process would be covered by higher user fees collected from sponsors seeking approval to market animal drugs, but we estimate that additional collections associated with activities required under the act would be negligible.

*Incentives to develop new drugs for animals.* The act would provide two incentives to encourage development of new animal drugs for minor uses and for minor species through the awarding of grants and of market exclusivity to qualifying sponsors of designated drugs.

First, the act would direct the FDA to award market exclusivity for seven years on the approved indication of certain designated drugs. As a result, a sponsor could sell its product without competition in the market and recover a portion of the research and development costs. CBO anticipates that the cost to the FDA associated with implementing this provision would be negligible.

Second, S. 741 would authorize the appropriation of specific amounts for making grants to sponsors of designated drugs in the two fiscal years following the issuance of final regulations for the new program and would authorize the appropriation of such sums as necessary in later years. Grants awarded under the program would defray some of the costs for qualified safety and effectiveness testing and for certain manufacturing expenses associated with developing the qualifying drug. Based on the time frame outlined in the act, CBO assumes that funding for grants would not be authorized until fiscal year 2007. We estimate that outlays for the new grant program would total $4 million over the 2007-2009 period, assuming the availability of appropriated funds.

*New Office.* S. 741 would establish a new Office of Minor Use and Minor Species Animal Drug Development within the Center for Veterinary Medicine at the FDA. The office would designate minor use and minor species drugs, administer grants authorized under the act, and review requests for listing of drugs on the newly created index. The act would authorize the appropriation of $1.2 million in 2004 and such sums as necessary in later years. Assuming the appropriation of the necessary amounts, CBO estimates that creating and funding the new office would cost $1 million in 2005 and $6 million over the 2005-2009 period.

**Title II: Food Allergen Labeling and Consumer Protection Act of 2004.** Title II of the act would direct the Secretary to engage in a number of activities to increase scientific and public understanding of issues related to food allergies. CBO estimates that implementing title II would cost $5 million in 2005 and $50 million over the 2005-2009 period, assuming the appropriation of the necessary amounts.

The act would amend the FFDCA to require that any food that contains a major food allergen be labeled in such a way that the presence of the food allergen is easily visible to consumers. Major food allergens are defined as "milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans." Section 203 also would provide for an appeal process whereby an individual or company could petition the Secretary to exempt a food ingredient from that labeling requirement. The Secretary would be required to approve or deny the petition within 180 days of receiving such an appeal. Based on information from the FDA, CBO estimates that spending by the FDA to carry out those responsibilities would amount to $1 million in 2005 and $5 million over the 2005-2009 period, assuming appropriation of the necessary funds.

The act also would direct the Secretary, through the Centers for Disease Control and Prevention (CDC), to engage in the collection of, and publication of data on the prevalence of food allergies, the incidence of serious adverse events related to food allergies, and the treatment and prevention of food allergies. Because true food allergy events are relatively rare (in contrast to food poisoning events), CBO expects that the CDC would engage in multiple strategies to identify and collect useful data, such as:

- Analyzing existing data, including questions recently added to the National Health Interview Survey (NHIS) to better assess the prevalence of known food allergies.

- Adding laboratory tests to the National Health and Nutrition Examination Survey (NHANES) to identify conditions that may be unknown to the survey participant.

- Testing stored blood specimens that were collected in a previous cycle of the NHANES, and stored for future analysis, to estimate the prevalence of food allergy reactivity in the U.S. population.

- Improving the ability of the nation's vital statistics system to monitor food allergy-related deaths by using intelligent automated systems to help physicians more accurately record cause of death, and by working with physicians' organizations to improve education on recording cause of death.

- Increasing the precision of surveys of health care providers, and improving the quality of information recorded by providers, so that comparatively small numbers of events could be better detected.

Based on information from the FDA and CDC, CBO estimates that federal spending to develop and operate the system for collecting data on food allergies would total $3 million in 2005 and $41 million over the 2005-2009 period, subject to appropriation of the necessary amounts.

The act would require the Secretary to submit a report to the Congress within 18 months of enactment. That report should analyze the extent to which foods are unintentionally contaminated with major food allergens during the manufacturing process, recommend manufacturing practices that would reduce the incidence of such contamination, and describe the types of advisory labeling currently being used by food producers, the extent to which such labeling is being used, and the preferences of those likely to be affected by food allergies regarding labeling information. Assuming the availability of appropriated funds, CBO estimates that the FDA would spend less than $500,000 in 2005 and a total of $1 million over the 2005-2009 period to produce that report.

S. 741 would require the Secretary to conduct inspections of food manufacturing, processing, and packing facilities to ensure that such entities are engaging in efforts to reduce the possibility of food allergen contamination and to ensure that food allergens are being appropriately labeled. Based on information provided by the FDA, CBO expects those tasks would be accomplished without increasing the number of inspections of food facilities and without having a significant effect on the cost of those inspections.

The act also would require the Secretary to develop guidelines for preparing allergen-free foods in food establishments (such as restaurants, bakeries, delicatessens, and cafeterias), and to issue regulations to define and permit the use of the term "gluten-free" on the labeling of foods. Based on information from the FDA about the cost of similar activities, CBO estimates that spending by the FDA to carry out those responsibilities would total $1 million in 2005 and $3 million over the 2005-2009 period.

## ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

S. 741 contains no intergovernmental mandates as defined in UMRA. The act's provisions would increase the availability and broaden the potential uses of certain drugs used to treat minor species animals and also to treat minor conditions in major species. State and local conservation programs, zoos, and animal shelters could take advantage of those new drugs or uses, and the impact on their budgets would likely be positive.

## ESTIMATED IMPACT ON THE PRIVATE SECTOR

S. 741 would impose private-sector mandates, as defined in UMRA, on the manufacturers, packagers and labelers of processed foods regulated by the Food and Drug Administration and on the manufacturers of certain animal drugs. CBO estimates that the direct cost of these mandates would not exceed the threshold established by UMRA ($120 million in 2004, adjusted annually for inflation) in any of the first five years the mandates would be effective.

Section 203 would require the labels of processed foods containing major food allergens to display the names of those allergens from which ingredients are derived. According to industry sources, the majority of the approximately 300,000 food labels regulated by the FDA are currently in compliance with the requirement of S. 741. Moreover, the requirement would not become effective until January 1, 2006, allowing many food processors to incorporate the required changes during planned label revisions, further decreasing the cost of the mandate. This compliance period also would provide food processors with sufficient time to exhaust most label inventories, resulting in small costs due to lost inventories. Based on information provided by the FDA and industry sources, CBO estimates that the administrative, printing, analytical, and label inventory costs associated with this mandate would total less than $75 million through fiscal year 2006, and would be negligible in later years.

Section 102 of the act also would impose private-sector mandates, as defined in UMRA, on some manufacturers of generic animal drugs for minor uses or use in minor species by providing additional market exclusivity to innovators. This additional exclusivity would potentially delay the time at which the generic products of some animal drug manufacturers could enter the market. Based on information provided by the FDA and the Department of Agriculture, CBO estimates the cost of these mandates to be small.

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