



**CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE**

July 23, 2014

H.R. 4250
Sunscreen Innovation Act

*As ordered reported by the House Committee on Energy and Commerce
on July 15, 2014*

SUMMARY

H.R. 4250 would modify the review process that allows the marketing of certain new ingredients in non-prescription sunscreen based on a determination by the Food and Drug Administration (FDA) that they are generally recognized as safe and effective. CBO estimates that implementing H.R. 4250 would cost \$28 million over the 2015-2019 period, assuming appropriation of the necessary amounts. H.R. 4250 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

H.R. 4250 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 allow FDA to require that marketing applications for certain sunscreen products be submitted in a new standardized format. CBO estimates that the direct cost of complying with those requirements would not exceed the annual threshold established by UMRA for private-sector mandates (\$152 million in 2014, adjusted annually for inflation).

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary effect of H.R. 4250 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					2015- 2019
	2015	2016	2017	2018	2019	

CHANGES IN SPENDING SUBJECT TO APPROPRIATION

Estimated Authorization Level	4	5	7	7	9	32
Estimated Outlays	3	4	6	7	8	28

BASIS OF ESTIMATE

For this estimate, CBO assumes that H.R. 4250 will be enacted near the beginning of fiscal year 2015, that the necessary amounts will be appropriated for each year, and that outlays will follow historical spending patterns for similar activities.

Drugs marketed in the United States generally must be tested for safety and efficacy and approved by FDA through an application process. However, certain products currently are marketed under a determination by FDA that they are generally recognized as safe and effective and have been marketed for a specific time and extent under the conditions of their labeling. Under current law, non-prescription sunscreen products are marketed under such a determination and are subject to a multistep process that involves scientific review and notice-and-comment rulemaking by FDA.

H.R. 4250 would change the process for reviewing certain new drug ingredients in non-prescription sunscreen by FDA. In addition, the bill would require that the agency adhere to specific timelines and issue administrative orders. Based on information provided by FDA, CBO estimates that implementing the bill would cost \$28 million over the 2015-2019 period, assuming appropriation of the necessary amounts.

PAY-AS-YOU-GO CONSIDERATIONS: None.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

H.R. 4250 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

H.R. 4250 would impose a mandate on firms seeking to market certain new active ingredients for sunscreen by giving FDA the authority to modify the format of marketing applications. Under current law, FDA can refuse to allow marketing of a sunscreen product if the agency finds that the sponsor does not provide sufficient data to demonstrate that the product is generally recognized as safe and effective. However, FDA currently cannot require that applicants submit their applications in a standardized format. Such lack of uniformity can slow down the review process. Under H.R. 4250, FDA would have the authority to impose and enforce a standard format on such applications. The number of applications for new sunscreen ingredients is low in any given year, and the additional cost to each sponsor of complying with the new requirements would be low as well. Therefore,

CBO expects that the cost of complying with this new requirement would not exceed the threshold defined in UMRA (\$152 million in 2014, adjusted annually for inflation) in any of the first five years following enactment.

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