Congressional Budget Office
Cost Estimate

May 1, 2019

H.R. 1503, Orange Book Transparency Act of 2019

As ordered reported by the House Committee on Energy and Commerce on April 3, 2019

By Fiscal Year, Millions of Dollars	2019	2019-2024	2019-2029
Direct Spending (Outlays)	0	0	0
Revenues	0	0	0
Deficit Effect	0	0	0
Spending Subject to Appropriation (Outlays)	0	1	n.e.

Pay-as-you-go procedures apply?	No	**Mandate Effects**	
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2030?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	Yes, Under Threshold

n.e. = not estimated.

Under current law, the Food and Drug Administration (FDA) publishes a compendium entitled, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book." The Orange Book identifies drug products approved on the basis of safety and effectiveness by FDA and provides associated patent and exclusivity information. FDA updates the Orange Book on a regular basis. H.R. 1503 would codify current regulations and practice regarding the types of patent and exclusivity-related information listed in the Orange Book.

H.R. 1503 also would require the prompt removal of certain patents from the Orange Book that have been invalidated by a ruling of the Patent Trial and Appeal Board at the United States Patent and Trademark Office.

The bill would require FDA to solicit public comments regarding the types of patent information that should be listed in the Orange Book. Within one year of enactment, FDA would be required to transmit to the Congress an evaluation of such comments, including any recommendations about the types of patent information that should be included on or removed from such list.

In addition, H.R. 1503 would direct the General Accountability Office (GAO) to conduct a study that analyzes certain patents with claims relating to devices listed in the Orange Book and evaluates the extent to which listing such patents has affected the timing for the entry of

generic drugs into the market. The bill would require GAO to submit the report to the Congress within one year of enactment.

Based on the costs of similar activities, CBO estimates that implementing the bill would cost $1 million, primarily for FDA's personnel-related expenses to comply with the bill's reporting requirements. Any such spending would be subject to the availability of appropriated funds.

H.R. 1503 would impose a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA) by requiring drug manufacturers to notify the FDA when the Patent Trial and Appeals Board or another court finds a drug patent to be invalid. CBO estimates the cost of the mandate would fall well below the private-sector threshold established in UMRA ($164 million in 2019, adjusted annually for inflation).

The CBO staff contacts for this estimate are Julia Christensen (for federal costs) and Andrew Laughlin (for mandates). The estimate was reviewed by Leo Lex, Deputy Assistant Director for Budget Analysis.