

115TH CONGRESS  
2D SESSION

# H. R. 4964

To amend the Federal Food, Drug, and Cosmetic Act to require that children’s cosmetics containing talc include an appropriate warning unless the cosmetics are demonstrated to be asbestos-free, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 7, 2018

Mrs. DINGELL introduced the following bill; which was referred to the  
Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require that children’s cosmetics containing talc include an appropriate warning unless the cosmetics are demonstrated to be asbestos-free, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Children’s Product  
5 Warning Label Act of 2018”.

1 **SEC. 2. LABELING OF TALC IN CHILDREN'S COSMETICS.**

2 (a) MISBRANDING.—Section 602 of the Federal  
3 Food, Drug, and Cosmetic Act (21 U.S.C. 362) is amend-  
4 ed by adding at the end the following:

5 “(g) If it is marketed for use in children (meaning  
6 individuals under the age of 18) and contains talc (as de-  
7 fined in section 604) unless—

8 “(1) its label includes the following statement  
9 printed in conspicuous text: ‘WARNING: Talc has  
10 not been evaluated for asbestos contamination. As-  
11 bestos at any level is known to the FDA to cause  
12 cancer, including lung cancer and mesothelioma and  
13 may be present in this product. This product is not  
14 suitable for use by children.’; or

15 “(2) a waiver is in effect with respect to the  
16 cosmetic pursuant to section 604.”.

17 (b) PREMARKET SAFETY VERIFICATION OF TALC  
18 CONTENT.—Chapter VI of the Federal Food, Drug, and  
19 Cosmetic Act (21 U.S.C. 361 et seq.) is amended by add-  
20 ing at the end the following:

21 **“SEC. 604. PREMARKET SAFETY VERIFICATION OF TALC**  
22 **CONTENT.**

23 “(a) IN GENERAL.—The Secretary shall waive the  
24 applicability of section 602(g)(1) with respect to a cos-  
25 metic containing talc if the manufacturer of the cos-  
26 metic—

1           “(1) attests in writing to the Secretary that the  
2 source of the talc is an asbestos-free mine; and

3           “(2) demonstrates to the Secretary that the talc  
4 is asbestos-free using the transmission electron mi-  
5 croscopy method.

6           “(b) DEFINITIONS.—In this section:

7           “(1) The term ‘asbestos’ means the asbestiform  
8 varieties of chrysotile (serpentine), crocidolite (rie-  
9 beckite), amosite (cummingtonitegrunerite), antho-  
10 phyllite, tremolite, and actinolite.

11           “(2) The term ‘asbestos-free’ means containing  
12 no traceable asbestos fibers.

13           “(3) The term ‘talc’—

14           “(A) means a basic silicate of magnesium;  
15 and

16           “(B) includes talcum powder, hydrous  
17 magnesium silicate, non-fibrous talc, non-  
18 asbestiform talc, steatite talc, and fibrous non-  
19 tremolite talc.

20           “(4) The term ‘transmission electron micros-  
21 copy’ refers to the asbestos analysis method used by  
22 laboratories that—

23           “(A) are accredited by the National Bu-  
24 reau of Standards; and

1           “(B) use the protocol described in appen-  
2           dix A to subpart E of part 763 of title 40, Code  
3           of Federal Regulations (or any successor regu-  
4           lations).”.

5           (c) APPLICABILITY.—Sections 602(g) and 604 of the  
6 Federal Food, Drug, and Cosmetic Act, as added by sub-  
7 sections (a) and (b), apply beginning on the date that is  
8 180 days after the date of enactment of this Act.

9           (d) REGULATIONS.—Not later than 180 days after  
10 the date of enactment of this Act, the Secretary of Health  
11 and Human Services, acting through the Commissioner of  
12 Food and Drugs, shall promulgate final regulations to im-  
13 plement such sections 602(g) and 604.

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