

Calendar No. 177

109TH CONGRESS
1ST SESSION

S. 172

[Report No. 109-110]

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of all contact lenses as medical devices, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 26, 2005

Mr. DEWINE (for himself, Mr. KENNEDY, Mr. ENZI, Mr. DORGAN, Ms. COLLINS, Mr. HARKIN, Mr. BURR, Mr. BUNNING, Mr. CORZINE, and Mr. VOINOVICH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JULY 27, 2005

Reported by Mr. ENZI, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of all contact lenses as medical devices, 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. FINDINGS.**

4 ~~Congress finds as follows:~~

1 (1) All contact lenses have significant effects on
2 the eye and pose serious potential health risks if im-
3 properly manufactured or used without appropriate
4 involvement of a qualified eye care professional.

5 (2) Most contact lenses currently marketed in
6 the United States, including certain plano and deco-
7 rative contact lenses, have been approved as medical
8 devices pursuant to premarket approval applications
9 or cleared pursuant to premarket notifications by
10 the Food and Drug Administration (“FDA”).

11 (3) FDA has asserted medical device jurisdic-
12 tion over most corrective and noncorrective contact
13 lenses as medical devices currently marketed in the
14 United States, including certain plano and decora-
15 tive contact lenses, so as to require approval pursu-
16 ant to premarket approval applications or clearance
17 pursuant to premarket notifications.

18 (4) All contact lenses can present risks if used
19 without the supervision of a qualified eye care pro-
20 fessional. Eye injuries in children and other con-
21 sumers have been reported for contact lenses that
22 are regulated by FDA as medical devices primarily
23 when used without professional involvement, and
24 noncorrective contact lenses sold without approval or

1 clearance as medical devices have caused eye injuries
2 in children.

3 **SEC. 2. REGULATION OF CERTAIN ARTICLES AS MEDICAL**
4 **DEVICES.**

5 Section 520 of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 360j) is amended by adding at the end
7 the following:

8 “Regulation of Contact Lens as Devices

9 “(n)(1) All contact lenses shall be deemed to be de-
10 vices under section 201(h).

11 “(2) Paragraph 1 shall not be construed as having
12 any legal effect on any article that is not described in that
13 paragraph.”

14 **SECTION 1. FINDINGS.**

15 *Congress finds as follows:*

16 (1) *All contact lenses have significant effects on*
17 *the eye and pose serious potential health risks if im-*
18 *properly manufactured or used without appropriate*
19 *involvement of a qualified eye care professional.*

20 (2) *Most contact lenses currently marketed in the*
21 *United States, including certain plano and decorative*
22 *contact lenses, have been approved as medical devices*
23 *pursuant to premarket approval applications or*
24 *cleared pursuant to premarket notifications by the*
25 *Food and Drug Administration (“FDA”).*

1 (3) *FDA has asserted medical device jurisdiction*
2 *over most corrective and noncorrective contact lenses*
3 *as medical devices currently marketed in the United*
4 *States, including certain plano and decorative contact*
5 *lenses, so as to require approval pursuant to pre-*
6 *market approval applications or clearance pursuant*
7 *to premarket notifications.*

8 (4) *All contact lenses can present risks if used*
9 *without the supervision of a qualified eye care profes-*
10 *sional. Eye injuries in children and other consumers*
11 *have been reported for contact lenses that are regu-*
12 *lated by FDA as medical devices primarily when used*
13 *without professional involvement, and noncorrective*
14 *contact lenses sold without approval or clearance as*
15 *medical devices have caused eye injuries in children.*

16 **SEC. 2. REGULATION OF CERTAIN ARTICLES AS MEDICAL**
17 **DEVICES.**

18 *Section 520 of the Federal Food, Drug, and Cosmetic*
19 *Act (21 U.S.C. 360j) is amended by adding at the end the*
20 *following:*

21 *“Regulation of Contact Lens as Devices*

22 *“(n)(1) All contact lenses shall be deemed to be devices*
23 *under section 201(h).*

1 “(2) Paragraph (1) shall not be construed as having
2 any legal effect on any article that is not subject to such
3 paragraph.”.

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