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109TH CONGRESS
1ST SESSION

H. R. 371

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 HOUSE OF REPRESENTATIVES

JANUARY 26, 2005

Mr. BOOZMAN (for himself and Mr. WAXMAN) 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 provide for the regulation of all contact lenses as medical devices, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. FINDINGS.

The Congress finds as follows:

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

(2) Most contact lenses currently marketed in the United States, including certain plano and deco-

rative contact lenses, have been approved as medical devices pursuant to premarket approval applications or cleared pursuant to premarket notifications by the Food and Drug Administration (''FDA'').

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

(4) All contact lenses can present risks if used without the supervision of a qualified eye care professional. Eye injuries in children and other consumers have been reported for contact lenses that are regulated by FDA as medical devices primarily when used without professional involvement, and noncorrective contact lenses sold without approval or clearance as medical devices have caused eye injuries in children.

SEC. 2. REGULATION OF CERTAIN ARTICLES AS MEDICAL DEVICES.

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

''Regulation of Contact Lens as Devices

''(n)(1) All contact lenses shall be deemed to be devices under section 201(h).

''(2) Paragraph 1 shall not be construed as having any legal effect on any article that is not described in that paragraph.''.

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