

BILL ANALYSIS

Senate Research Center
78R991 YDB-D

S.B. 1400
By: Nelson
Health & Human Services
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As Filed

DIGEST AND PURPOSE

In 1997, the United States Congress enacted the Food and Drug Administration Modernization Act which deleted or modified numerous sections of the Federal Food and Drug and Cosmetic Act. As proposed, S.B. 1400 revises the Texas Food and Drug and Cosmetic Act to conform Texas prescription drug labels to current federal statutes.

RULEMAKING AUTHORITY

This bill does not expressly grant any additional rulemaking authority to a state officer, institution, or agency.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Section 431.002(8), Health and Safety Code, to delete references in the definition of “consumer commodity.”

SECTION 2. Amends Section 431.042(c), Health and Safety Code, to delete a reference to current statute from existing text.

SECTION 3. Amends Section 431.059(b), Health and Safety Code, to delete and add a new reference to existing text.

SECTION 4. Amends Section 431.112, Health and Safety Code, as follows:

(d) Deletes entire text of existing Subsection (d).

Redesignates Subsections (e)-(u) as Subsections (d)-(t).

(j) Deletes Subdivisions (1) and (2) from existing text.

(k) Deletes Subdivisions (1) and (2) from existing text.

(o) Makes a nonsubstantive and a clarifying change.

SECTION 5. Amends Section 431.113(c), Health and Safety Code, to delete text from Subsection (c)(1)(a) and renumber subsequent subdivisions accordingly. Makes conforming changes to Subsection (c)(2). Deletes current text of (c)(3) and requires a drug that is subject to Subdivision (1) to be deemed to be misbranded if at any time prior to dispensing its label fails to bear at a minimum, the symbol “RX Only.”

SECTION 6. Amends Section 431.114(b), Health and Safety Code, to delete a reference in existing text.

SECTION 7. Makes application of this Act prospective.

SECTION 8. (a) and (b) Make application of this Act prospective.

SECTION 9. Effective date: September 1, 2003.