

Bill No. CS for CS for SB 370

Amendment No.      Barcode 943534

<u>Senate</u>	CHAMBER ACTION	<u>House</u>
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Senator Saunders moved the following **amendment to amendment**  
(104940):

**Senate Amendment (with title amendment)**

On page 97, between lines 23 and 24,

insert:

Section 80. Subsection (2) of section 499.007, Florida Statutes, is amended to read:

499.007 Misbranded drug or device.--A drug or device is misbranded:

(2) Unless, if in package form, it bears a label containing:

(a) The name and place of business of the manufacturer or distributor; ~~in addition, for a medicinal drug, as defined in s. 499.003, the label must contain the name and place of business of the manufacturer~~ of the finished dosage form of the drug. For the purpose of this paragraph, the finished dosage form of a medicinal drug is that form of the drug which is, or is intended to be, dispensed or administered to the patient and requires no further manufacturing or processing

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1 other than packaging, reconstitution, and labeling; and  
2 (b) An accurate statement of the quantity of the  
3 contents in terms of weight, measure, or numerical count;  
4 however, under this section, reasonable variations are  
5 permitted, and the department shall establish by rule  
6 exemptions for small packages.

7  
8 A drug dispensed by filling or refilling a written or oral  
9 prescription of a practitioner licensed by law to prescribe  
10 such drug is exempt from the requirements of this section,  
11 except subsections (1), (8), (10), and (11) and the packaging  
12 requirements of subsections (6) and (7), if the drug bears a  
13 label that contains the name and address of the dispenser or  
14 seller, the prescription number and the date the prescription  
15 was written or filled, the name of the prescriber and the name  
16 of the patient, and the directions for use and cautionary  
17 statements. This exemption does not apply to any drug  
18 dispensed in the course of the conduct of a business of  
19 dispensing drugs pursuant to diagnosis by mail or to any drug  
20 dispensed in violation of subsection (12). The department  
21 may, by rule, exempt drugs subject to ss. 499.062-499.064 from  
22 subsection (12) if compliance with that subsection is not  
23 necessary to protect the public health, safety, and welfare.

24  
25 (Redesignate subsequent sections.)

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28 ===== T I T L E A M E N D M E N T =====

29 And the title is amended as follows:

30 On page 107, line 21, after the semicolon

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1 insert:  
2           amending s. 499.007, F.S.; redefining  
3           circumstances that cause a drug or device to be  
4           considered misbranded;  
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