

Bill No. CS/HB 507, 2nd Eng.

Amendment No. Barcode 075450

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| <u>Senate</u> | CHAMBER ACTION | <u>House</u> |
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11 Senator Saunders moved the following **amendment to amendment**
 12 (455272):

14 **Senate Amendment (with title amendment)**

15 On page 97, between lines 23 and 24,
 16
 17 insert:

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

20 499.007 Misbranded drug or device.--A drug or device
 21 is misbranded:

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

24 (a) The name and place of business of the manufacturer
 25 or distributor; ~~in addition, for a medicinal drug, as defined~~
 26 ~~in s. 499.003, the label must contain the name and place of~~
 27 ~~business of the manufacturer~~ of the finished dosage form of
 28 the drug. For the purpose of this paragraph, the finished
 29 dosage form of a medicinal drug is that form of the drug which
 30 is, or is intended to be, dispensed or administered to the
 31 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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27
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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