

Amendment No. 4 (for drafter's use only)

	<u>Senate</u>	CHAMBER ACTION	<u>House</u>
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ORIGINAL STAMP BELOW

11 Representative(s) Farkas and Fasano offered the following:

13 **Amendment to Amendment (121137) (with title amendment)**

14 On page 105, between lines 24 & 25, of the amendment

16 insert:

17 Section 101. Paragraph (a) of subsection (2) of
18 section 499.007, Florida Statutes, is amended to read:

19 499.007 Misbranded drug or device.--A drug or device
20 is misbranded:

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

23 (a) The name and place of business of the manufacturer
24 or distributor; ~~in addition, for a medicinal drug, as defined~~
25 ~~in s. 499.003, the label must contain the name and place of~~
26 ~~business of the manufacturer~~ of the finished dosage form of
27 the drug. For the purpose of this paragraph, the finished
28 dosage form of a medicinal drug is that form of the drug which
29 is, or is intended to be, dispensed or administered to the
30 patient and requires no further manufacturing or processing
31 other than packaging, reconstitution, and labeling; and

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1 ===== T I T L E A M E N D M E N T =====
2 And the title is amended as follows:
3 On page 116, line 7, of the amendment, after ; of the
4 amendment
5
6 insert:
7 amending s. 499.007, F.S.; deleting requirement
8 for labeling of name and place of business of
9 the manufacturer;
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