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LEGISLATIVE ACTION

Senate	.	House
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Floor: 5/AD/2R	.	
03/08/2012 02:17 PM	.	
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Senator Hays moved the following:

Senate Amendment (with title amendment)

Between lines 1001 and 1002

insert:

(3)(a) A nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state in limited quantities intended for research and development and not for resale or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer claiming to be exempt from the permit requirements of this paragraph and the prescription drug manufacturer

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purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212. The prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; if available, the out-of-state license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers from whom they purchase active pharmaceutical ingredients under this section. The department shall define the term "limited quantities" by rule, and may include the allowable number of transactions within a given period of time and the amount of prescription drugs distributed into the state for purposes of this exemption. The failure to comply with the requirements of this paragraph, or rules adopted by the department to administer this paragraph, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(4).

(Redesignate subsequent paragraphs)

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

And the title is amended as follows:

Delete line 83

and insert:

prescription drugs; providing an exemption from permit requirements for the distribution into this state of prescription drug active pharmaceutical ingredients

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intended for research and development; requiring compliance with certain recordkeeping requirements; providing for a definition; providing for penalties; providing an exemption from permit