

Amendment No.

CHAMBER ACTION

Senate

House

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1 Representative Bean offered the following:

2
3 **Amendment**

4 Between lines 1507 and 1508, insert:

5 3. A nonresident prescription drug manufacturer permit is
6 not required for a manufacturer to distribute an active
7 pharmaceutical ingredient that it manufactures to a Florida
8 permitted prescription drug manufacturer in limited quantities
9 intended for research and development and not for resale or
10 human use other than lawful clinical trials and biostudies
11 authorized and regulated by federal law. A manufacturer claiming
12 to be exempt from the permit requirements of this paragraph and
13 the prescription drug manufacturer purchasing and receiving the
14 active pharmaceutical ingredient must comply with the
15 recordkeeping requirements of s. 499.0121(6), and rules adopted
16 thereunder. The department shall specify by rule the allowable

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17 | number of transactions within a given period of time and the
18 | amount of active pharmaceutical ingredients that qualify as
19 | limited quantities for purposes of this exemption.