

HB0316/926382/1

BY: Health and Government Operations Committee

AMENDMENTS TO HOUSE BILL 316
(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in the sponsor line, strike “and Kipke” and substitute “, Kipke, Hammen, Pendergrass, Bromwell, Cullison, Donoghue, Elliott, Frank, Kach, A. Kelly, Krebs, McDonough, Morhaim, Murphy, Nathan-Pulliam, Oaks, Pena-Melnyk, Ready, Reznik, and Tarrant”; in line 2, after “Permits - ” insert “Permit and”; in line 4, after “of” insert “exempting a manufacturer that distributes its own prescription devices that are approved or authorized by the U.S. Food and Drug Administration from certain permit requirements;”; in line 9, after “applicant;” insert “making stylistic changes;”; and in line 19, after “Section” insert “12-6C-03(b) and”.

AMENDMENT NO. 2

On page 2, after line 7, insert:

“12-6C-03.

(b) (1) A manufacturer engaged in wholesale distribution shall hold a wholesale distributor permit issued under this subtitle.

(2) Notwithstanding paragraph (1) of this subsection, the information and qualification requirements for obtaining a permit under this subtitle, beyond that required by federal law, do not apply to [a]:

(I) A manufacturer [who] THAT distributes its own prescription drugs THAT ARE approved by the U.S. Food and Drug Administration; OR

(Over)

(II) A MANUFACTURER THAT DISTRIBUTES ITS OWN PRESCRIPTION DEVICES THAT ARE APPROVED OR AUTHORIZED BY THE U.S. FOOD AND DRUG ADMINISTRATION.”.