HOUSE AMENDMENT

hbd-06 Bill No. <W>HB 3871</W>

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

CHAMBER ACTION

<W>Senate</W>

<W>House</W>

ORIGINAL STAMP BELOW

Representative(s) Ritter offered the following:

Amendment

On page 3, lines 4-18,

remove from the bill: all of said lines

and insert in lieu thereof:

(2) In a product liability action against a manufacturer or seller, it shall be an affirmative defense that a product that is a drug as defined in Section 201(g)(1) of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. 321(g)(1), or a medical device as defined in Section 201(h) of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. 321 (h), is not defective or unreasonably dangerous if the drug or device was approved for safety and efficacy by the United States Food and Drug Administration and the drug or medical device and its labeling were in compliance with the United States Food and Drug Administration's approval at the time the drug or medical device left the control of the manufacturer or seller. However, this subsection does not apply to a drug or medical device that is sold in the United States after the

effective date of an order of the United States food and Drug Administration to remove the product from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following.