U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Record of Commission Action
Commissioners Voting by Ballot*

Commissioners Voting: Chairman Hal Stratton
Commissioner Thomas H. Moore
Commissioner Mary Sheila Gall

ITEM:

Final Rule to Exempt Hormone Replacement Therapy ("HRT") Products from Special Packaging Requirements

DECISION:

The Commission voted unanimously (3-0) to approve a Federal Register notice issuing a final rule to exempt hormone replacement therapy ("HRT") products from the special packaging requirements of the Poison Prevention Packaging Act. Commissioner Moore filed a statement regarding his vote, copy attached.

For the Commission:

Todd A. Stevenson
Secretary

* Ballot vote due October 23, 2002

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STATEMENT OF THE HONORABLE THOMAS H. MOORE IN SUPPORT OF ISSUANCE OF A FINAL RULE TO EXEMPT HRT PRODUCTS FROM SPECIAL PACKAGING REQUIREMENTS

October 24, 2002

Today I have voted to issue a final rule to exempt hormone replacement therapy products containing one or more progestogen or estrogen substances from the special packaging requirement of the PPPA. According to a Commission rule, oral prescription drugs must be in child resistant packaging. However, the Commission has the authority to exempt particular substances that have low acute toxicity from this requirement. Currently, there are four exemptions for sex hormones under the PPPA. Interestingly, there are a number of hormone replacement therapy products requiring child resistant packaging that contain the same or similar sex hormones as those in exempted products. This final rule will simply provide uniformity by exempting from child resistant packaging requirements all hormone replacement therapy products that rely solely on the activity of one or more progestogen or estrogen substances.

Notwithstanding, I am aware of recent studies that have raised questions of the health effects of long-term use of hormone replacement therapy products. However, the negative observations associated with long-term use do not translate into increased concerns about acute toxicity. The risks associated with chronic hormone therapy are not expected in children after a single acute ingestion. All available data continue to indicate that sex hormones (estrogen and progestogen) have low acute toxicity.

I think that it is very important that there is absolutely no confusion in the public about the distinction between acute toxicity and chronic long-term effects. Therefore I strongly urge our public affairs office to emphasize this distinction in any public announcement of the Commission's vote to issue this final rule.