United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: May 7, 2002

TO : HS

Through: Todd A. Stevenson, Secretary, OS

FROM : Martha A. Kosh, OS

SUBJECT: Proposed Rule to Exempt Hormone Replacement Therapy (HRT) Products from the Special Packaging Requirements of the Posion Prevention Packaging Act

ATTACHED ARE COMMENTS ON THE CP 02-1

COMMENT	DATE	SIGNED BY	AFFILIATION
CP 02-1	4/17/02	Michael Doroshuk Manager, Drug Regulatory Affairs	Berlex Drug Development & Technology 340 Changebridge Rd. P.O. Box 1000 Montiville, NJ 07045

BERLEX

2nd Day UPS

Drug Development & Technology
Division of Berlex Laboratories, Inc.

340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045-1000
Telephone: (973) 487-2000

April 17, 2002

U.S. Consumer Product Safety Commission - Office of the Secretary - Room 502
4330 East-West Highway
Bethesda, Maryland 20814-4408
Attention: Jacqueline Ferrante, Ph.D. Room 600-08

Dear Dr. Ferrante:

Re: Proposed Rule to Exempt Hormone Replacement Therapy (HRT) Products from the Special Packaging Requirements of the Poison Prevention Packaging Act

Reference is made to the Federal Register notice dated February 19, 2002 (Volume 67, Number 33, page 7319 ff.), proposing to exempt all HRT products that rely solely on the activity of one or more progestogen or estrogen substances from child resistant (CR) packaging requirements.

Berlex Laboratories, Inc. ("Berlex"), a subsidiary of Schering AG, Germany, is a leading supplier of hormones to the U.S. market. Berlex has a major US presence in the area of female healthcare, with products for estrogen replacement therapy (ERT), long-acting contraception, and oral contraception. Berlex plans to enter the oral HRT market soon and finds the consistency of packaging for our oral contraception and oral HRT products, as proposed, to be beneficial in terms of costs and efficiency.

Berlex strongly supports the proposed amendment. As noted in the Federal Register announcement, progestogens and estrogens are generally considered to be of low acute toxicity, and the same types of substances are used in oral contraceptives which are already exempt from CR packaging requirements. Therefore, the exemption should be extended to HRT products. In addition, this exemption will give drug producers greater flexibility in meeting the needs of the HRT patient population.

If you have questions or if we can be of further assistance, please contact the undersigned at (973) 487-2184, FAX (973) 487-2016, or email: *michael_doroshuk@berlex.com.*

Sincerely,

BERLEX LABORATORIES

Michael Doroshuk
Manager, Drug Regulatory Affairs