

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

**APPLICATION NUMBER
20-524/S-005**

Chemistry Review(s)

The firm should revise the word " By" to lower case "by"
(package insert only).

Under Carton and Container Labels:

The carton and packaging labels reflect:

Manufacture by: DPT Laboratories
San Antonio, TX 78215

Distributed by: BERTEK PHARMACEUTICALS INC.
Morgantown, WV 26505

18. **CONCLUSIONS AND RECOMMENDATIONS**
Recommend approval letter to issue for this supplement.

cc: Orig: NDA 20-524
HFD-540
HFD-540/Vaughan
HFD-540/Mainig
HFD-520/Cross
HFD-540/EGPappas
HFD-540/WHDeCamp:R/D initialed _ 1/23/01

19. REVIEWER		
NAME	SIGNATURE	DATE COMPLETED
Ernest G. Pappas	<i>ES</i>	01/23/01

DISTRIBUTION	ORIGINAL JACKET	REVIEWER	DIVISION FILE
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