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SMITH KLINE & FRENCH LABORATORIES

1500 Spring Garden St., P.O. Box 7929, Philadelphia, PA 19101 • 215-854-4000

cable SMITHKLINE PHILADELPHIA
telex 83-4487

December 14, 1979

NDA 83-900

Special new drug application
Supplement - changes being effected

FDA, Bureau of Drugs
HFD #530 ; Document Control Room # 16-72
5600 Fishers Lane
Rockville, Maryland 20857

NDA NO. 12706 REF. NO. 57008
NDA SUPPL FOR Label Rev

FPL

Gentlemen:

In accordance with 314.8 (d)(e) and in response to the Federal Register notice of August 25, 1978 ("Prescription Drug Dispensing Container Requirements"), I have enclosed 12 final printed copies of the immediate container label for:

'Benzedrine' (brand of amphetamine sulfate) Tablets, 5 mg. (100's)

revised to add

"Dispense in a tight, light-resistant container."

This labeling will be placed in use in January, 1980.

Sincerely yours,

J. F. Cassin

J.F. Cassin
Manager, Regulatory Affairs

JFC/slh

Enclosures

DEC 17 1979

Immediate container label
'Benzedrine' (brand of amphetamine sulfate) Tablets
5 mg. (100's)

NDA 83-900

Labeling: Cris

NDA No: 83-900

Re'd. 12/12/79

Reviewed by: W. H. New

2/7/81

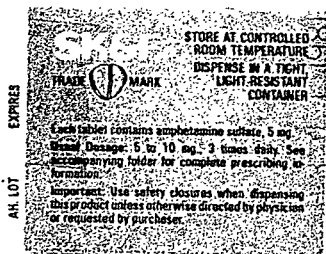


100 tablets
NDC 0007-3191-20 5 mg.

CAUTION - Federal law prohibits dispensing without prescription.

Benzedrine
brand of
amphetamine sulfate
Tablets

Smith Kline & French Laboratories
Div. of SmithKline Corp., Phila., Pa. 19101

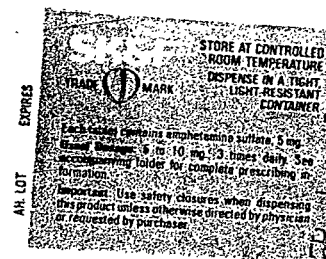


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