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SMITH KLINE & FRENCH LABORATORIES

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February 6, 1979

NDA 83-900

Special new drug application
Supplement - changes being effected

NDA NO. 896 REF. NO. 57006
NDA SUPPL FOR Label Rev

Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs, HFD #530
Document Control Room #16-72
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

FPL

Gentlemen:

In accordance with 314.8 (d)(e), I have enclosed 12 final printed copies of the immediate container label for 'Benzedrine' (brand of amphetamine sulfate) Tablets, 10 mg. (100's) revised:

- a) to add the word "Tablets" to the product name;
- b) to reposition the NDC number on the right-hand side of this single-panel label;
- c) under USUAL DOSAGE, to change "prescribing data" to "prescribing information".

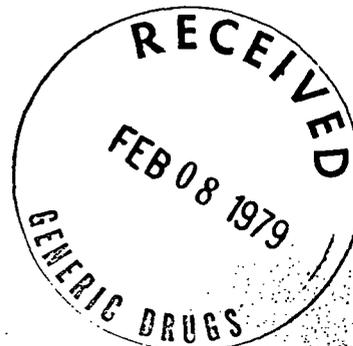
This labeling is scheduled to be placed in use in March, 1979.

Sincerely yours,

J. F. Cassin

J.F. Cassin
Manager, Regulatory Affairs

JFC/slh
Enclosures



Immediate container label
'Benedrine' (brand of amphetamine sulfate) Tablets
10 mg. (100's)

NDA 83-900

Labeling: Chris
NDA No: 83 900 Rev. 2 & 79
Reviewed by: _____

100's

EXPRES

AG. LOT

STORE AT CONTROLLED ROOM TEMPERATURE

TRADE MARK

Each tablet contains amphetamine sulfate, 10 mg. Usual Dosage: 5 to 10 mg., 3 times daily. See accompanying folder for complete prescribing information.

Important: Use safety closures when dispensing this product unless otherwise directed by physician or requested by purchaser.

100 tablets
NDC 0807-3192-20

10 mg.

CAUTION - Federal law prohibits dispensing without prescription.

Benedrine
brand of
amphetamine sulfate
Tablets

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