

83900.SI

NDA 83-900/S-001

APR 15 1976

Smith Kline & French Laboratories
Attention: J.F. Cassin
1500 Spring Garden Street
P.O. Box 7929
Philadelphia, PA 19101

Gentlemen:

We acknowledge receipt on March 31, 1976, of your communication of March 31, 1976. This is regarded as a supplemental new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Benzedrine (Amphetamine Sulfate) Tablets, 5 mg. and 10 mg.

✓ The supplemental application provides for manufacturing revisions.

✓ We have completed the review of this supplemental application and it is approved. Our letter of February 26, 1976, detailed the conditions relating to the approval of this application.

The material submitted is being retained in our file.

Sincerely yours,

/S/

for
Marvin Seife, M.D. *4/15/76*
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

cc:
PHI-DO
Dup

HFD-614 HFD-616

JLMeyer/MJarski *MJarski 4/14/76*

R/D init. JMeyer/MSeife 4-14-76

Final typing/wlb/4-15-76

Approved *JMeyer 4/14/76*

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER

83-900

DATE APPROVAL LETTER ISSUED

APR 15 1976

TO:

Press Relations Staff (HF1-40)

PROM:

Bureau of Drugs

Bureau of Veterinary Medicine

Forward original of this form for production of approval letter when issued and the date of approval has been entered above.

ABBREVIATED

TYPE OF APPLICATION

ORIGINAL NDA

SUPPLEMENT TO NDA

ABBREVIATED ORIGINAL NDA

SUPPLEMENT TO ANDA

CATEGORY

HUMAN

VETERINARY

TRADE NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG.

Benzedrine (Amphetamine Sulfate)

DOSAGE FORM

Tablet

HOW DISPENSED

RX

OTC

ACTIVE INGREDIENT(S) (as declared on label. List by established or nonproprietary name(s) and include amount(s), if amount is declared on label.)

Amphetamine Sulfate, 5 mg. and 10 mg.

NAME OF APPLICANT (Include City and State)

Smith Kline & French Laboratories
Philadelphia, PA 19101

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY

amphetamine

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

manufacturing revision

FORM PREPARED BY

NAME majarski

DATE

FORM APPROVED BY

NAME

flmeyer

DATE

SMITH KLINE & FRENCH LABORATORIES

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

cable SMITHKLINE PHILADELPHIA PA
telex 83-4487

March 31, 1976

NDA 83-900
'Benzedrine'
Tablets

NDA NO. 83900 REF. NO. 51001
Manufacturer: SmithKline Chem.

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 20852

Gentlemen:

In accordance with the commitment in our amendment dated February 19, 1976 to our New Drug Application #83-900 for 'Benzedrine' (amphetamine sulfate) Tablets, Page 1 of Section 8 of our Methods, Facilities and Controls used for the product has been revised to reflect that the designation DMF has been assigned to our Drug Master File describing the methods, facilities and controls used for the production of the drug substance Amphetamine Sulfate (copy attached).

Sincerely,

J.F. Cassin

J. F. Cassin
Manager, Regulatory Affairs

Att.
kb

