839005-S7

MAY 11 1982

NDA 83-900/S-007

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

Gentlemen:

Reference is made to your supplement dated September 14, 1979, regarding your abbreviated 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.

Also referenced is your letter of February 11, 1982.

The supplemental application provides for updated component, composition, and methods/facilities/controls information.

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.

Please be advised that an extension of expiration date must be requested as a supplemental application with supporting data.

Also, although approved, the information in this supplement (S-007) should again be updated to reflect the new compendial references (USP XX/NF XV).

The material submitted is being retained in our files.

Sincerely yours,

/S/ 5/11/82

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

cc: PHI-DO

HFD-616
HFD-534 (H. Zell)
HZell/KJFurnkranz
R/D INITIAL HZell/MSeife
mstephens: 5/7/82(7729A)
approved
KJFurnkranz May 7, 1982
HCZell 5/10/82

NDA 83-900 CHEMIST'S REVIEW FOR ANDA OR SUPPLEMENT

NAME AND ADDRESS OF APPLICANT:
Smith Kline & French
Philadelphia, PA

DATE(S) OF SUBMISSION(S)

S-007	September 14, 1979
S/NC	September 20, 1979
S/NC	August 11, 1980
S/NC	November 30, 1981

PHARMACOLOGICAL CATEGORY	NAME OF DRUG	HOW DISPENSED
Amphetamine	Benzedrine (Amphetamine) Sulfate	RX

DOSAGE FORM	POTENCY	STERILIZATION
Tablet	5 mg & 10 mg	NA

SAMPLES
NA

LABELING
NA

BIOLOGIC AVAILABILITY
NA

ESTABLISHMENT INSPECTION
NA

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS
S-007 Update to Components, Composition, Manufacturing & Controls

PACKAGING
NA

STABILITY
S/NC - received stability data (Ack & Ret)

REMARKS AND CONCLUSION
R-010 NAI
S-007 Approve
S/NC (4) Ack & Ret
KJFurnkranz

May 10, 1982 5/10/82

SK&F
a SmithKline company

SMITH KLINE &FRENCH LABORATORIES
1500 Spring Garden St., P.O. Box 7929, Philadelphia, PA 19101 • 215-854-4000

cable SMITHKLINE PHILADELPHIAPA
telex 83-4487

September 14, 1979

NDA 83-900

Marvin Seife, M.D.
Director, Division of Generic Drug Monographs
Food and Drug Administration
HFD #530; Document Room #16-72
5600 Fishers Lane
Rockville, Maryland 20857

NDA NO. 83 900 REF. NO. 5/SC7
NDA SUPPL FOR Control Rx

Dear Doctor Seife:

This supplement on 'Benzedrine' Tablets is submitted to provide updated information with respect to items 6 (components), 7 (composition) and 8 (methods, facilities and controls). FPL

Submission of this supplement at this time should not be construed to waive or in any other manner affect our right to a hearing as provided for in the FR notice of July 17, 1979 (p. 41552-72) regarding the proposed removal of the indication for short-term adjunctive treatment in obesity from amphetamine products.

Sincerely yours,

J. F. Cassin

J.F. Cassin
Manager, Regulatory Affairs

JFC/slh

Enclosures

RECEIVED
SEP 17 1979
GENERIC DRUGS

SK&F
a SmithKline company

SMITH KLINE &FRENCH LABORATORIES
1500 Spring Garden Street, P.O. Box 7929, Philadelphia, PA 19101 • (215) 751-4000

cable SMITHKLINE PHILADELPHIAPA
telex 83-4487

February 11, 1982

NDA 83-900

SUPPL NEW CORRES

Marvin Seife, M.D.
Director, Division of Generic Drug Monographs
Food and Drug Administration
HFD #530; Document Room #16-72
5600 Fishers Lane
Rockville, Maryland 20857

w ltr 5/10/82
5/07

Dear Doctor Seife:

On September 14, 1979 we submitted a supplemental application for 'Benzedrine' (amphetamine sulfate) Tablets to provide for updated information with respect to items 6 (components), 7 (composition) and 8 (methods, facilities and controls). To date no response has been received regarding this submission.

We would appreciate acknowledgement of receipt and/or any communication issued pertaining to this document. If you never received it, we wish to refile the document to complete our records.

Sincerely yours,

J.F. Cassin

J.F. Cassin
Director, Regulatory Editing
and Advertising Review

JFC/slh

RECEIVED
FEB 16 1982
GENERIC DRUGS