839005-3,4

[redacted] 21 1978

NDA 83-900/S-003
S-004

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

Gentlemen:

Reference is made to your supplements dated September 11, 1978, regarding your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amphetamine Sulfate Tablets, 5 mg. and 10 mg.

The supplemental applications provide for:

S-002 A revised formula

S-003 Manufacturing and control revisions attendant to the new formula.

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 as part of your application.

Sincerely yours,

/S/ 11/21/78

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

cc:
PHI-DO DUP HFD-614
JMeyer/MJarski
r/d init. JMeyer/MSeife 11-20-78
f/t/wlh/11-20-78
approved.

JMeyer 11/20/78
mjarski 11/20/78

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER: 83-900

DATE APPROVAL LETTER ISSUED:

TO: Press Relations Staff (HFI-40)

FROM:
- [X] Bureau of Drugs
- [ ] Bureau of Veterinary Medicine

NOV 21 1978

ATTENTION

Forward original of this form for publication only after approval letter has been issued and the date of approval has been entered above.

ABBREVIATED

TYPE OF APPLICATION
- [ ] ORIGINAL NDA
- [ ] SUPPLEMENT TO NDA
- [ ] ABBREVIATED ORIGINAL NDA
- [ ] ABBREVIATED SUPPLEMENT

CATEGORY
- [X] HUMAN
- [ ] VETERINARY

TRADE NAME *(or other designated name)* AND ESTABLISHED OR PROPRIETARY NAME OF DRUG

amphetamine sulfate

DOSAGE FORM

tablet

HOW DISPENSED
- [X] 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 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 & control revisions

FORM PREPARED BY

NAME: majarski DATE:

FORM APPROVED BY

NAME: jlmeyer DATE:

FORM FD 1642 (2/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

CHECKLIST & REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Statement Date:	NDA NUMBER: 83-900/S-003 S-004

NAME AND ADDRESS OF APPLICANT

Smith Kline & French Laboratories
Philadelphia, PA 19101

ORIGINAL
AMENDMENT
SUPPLEMENT xxxx
RESUBMISSION
CORRESPONDENCE
REPORT
OTHER

PURPOSE OF AMENDMENT/SUPPLEMENT

revised formula and manufacturing and control changes

DATE(s) of SUBMISSION(

9-11-78

PHARMACOLOGICAL CATEGORY	NAME OF DRUG	HOW DISPENSED
amphetamine	amphetamine sulfate	RX xxxxx OTC
DOSAGE FORM(S)	POTENCY(IES)	RELATED IND/NDA/DMF
tablet	5 and 10 mg.	
STERILIZATION	SAMPLES	

LABELING

BIOLOGIC AVAILABILITY

ESTABLISHMENT INSPECTION

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

satisfactory

PACKAGING

STABILITY
Protocol:

Exp. Date:

REMARKS AND CONCLUSION: approval majarski

(/S/) 11/20/78

SKGF

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 11, 1978

NDA 83-900
'Benzedrine' Tablets

NDA NO 8-900 REF. NO. -900-

NDA SUPPL FOR Formula Rev

S-004 manuf + Control Revision

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

Gentlemen:

Our New Drug Application for 'Benzedrine' (amphetamine sulfate) Tablets provides for the use of FD&C Red #2 as a coloring component of the product. As a result of the Federal Register notice dated February 10, 1976 (pages 5823-5825), which terminated the provisional listing of FD&C Red #2 for use in food, drugs and cosmetics the colorant composition was reformulated to use D&C Red #33 and D&C Yellow #10 in place of FD&C Red #2 and FD&C Yellow #5.

This supplement is submitted in accordance with the provisions of §314.8(d)(3) and (e) to provide for this reformulation.

The change in colorant composition did not interfere with any assay or other control procedures used in manufacturing the drug product. Stability data obtained to date on a representative batch of the 10 mg. strength product is attached. Additional stability data will be submitted as it becomes available. Appropriate action will be taken on any marketed batches which may become subpotent.

Sincerely,

J. F. Cassin

J. F. Cassin
Manager, Regulatory Affairs

RECEIVED
SEP 11 1978
GENERIC DRUGS

att.
jm

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 18, 1979

NDA 83-900/S-003, S-004
'Benzedrine' Tablets

SUPPL NEW CORRES

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

Gentlemen:

In accordance with our prior commitment, submitted herewith is updated stability data for a representative batch of 'Benzedrine' Tablets reformulated as described in our supplemental application S-003, S-004 dated September 11, 1978 as approved November 21, 1978. Additional stability data will be submitted periodically as it becomes available.

Sincerely,

J. F. Cassin

J. F. Cassin
Manager, Regulatory Affairs

att.
jm

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

August 11, 1980

NDA 83-900/S-003, S-004
'Benzedrine' Tablets

SUPPL NEW CORRES

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

Gentlemen:

In accordance with our prior commitment, submitted herewith is updated stability data for a representative batch of 'Benzedrine' Tablets reformulated as described in our supplemental application S-003, S-004 dated September 11, 1978 as approved November 21, 1978. Additional stability data will be submitted periodically as it becomes available.

Sincerely,

J. F. Cassin

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

kmcs

Attachment