

839005-3,4

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,

Marvin Seife, M.D.

Director

Division of Generic Drug Monographs

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.

Handwritten: JMeyer/hd/x
mjski
11/20/78

NOTICE OF APPROVAL NEW DRUG APPLICATION OR SUPPLEMENT		NDA NUMBER 83-900
TO: Press Relations Staff (HFI-40)		FROM: ☒ 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.		
TYPE OF APPLICATION ☐ ORIGINAL NDA ☐ SUPPLEMENT TO NDA ☐ ABBREVIATED NEW DRUG APPLICATION CATEGORY ☒ HUMAN ☐ VETERINARY		
TRADE NAME (or other designated name) AND ESTABLISHED OR PROPRIOETARY NAME OF DRUG 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 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

CHIEF'S 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

amphetamine

NAME OF DRUG

amphetamine sulfate

HOW DISPENSED

RX xxxxx OTC

DOSAGE FORM(S)

tablet

POTENCY(IES)

5 and 10 mg.

RELATED IND/NDA/DMF

STERILIZATION

SAMPLES

LABELING

BIOLOGIC AVAILABILITY

ESTABLISHMENT INSPECTION

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

satisfactory

PACKAGING

STABILITY

Protocol:

Exp. Date:

REMARKS AND
CONCLUSION:

approval majarski

(/S/ ii) 11/20/78

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

September 11, 1978

NDA 83-900

'Benzedrine' Tablets

NDA NO. 83-900 REF. NO. 100-

NDA SUPPL FOR Formulation Rev

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

S-004 manu +
Control Rev: 8/28/78

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

att.
jm



SMITH KLINE & FRENCH LABORATORIES

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

PKS
cable SMITHKLINE PHILADELPHIA PA
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



MS

SMITH KLINE & FRENCH LABORATORIES

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

cable SMITHKLINE PHILADELPHIA
telex 83-4487

August 11, 1980

NDA 83-900/S-003, S-004
'Benedrine' 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 'Benedrine' 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

