

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

83900

CHEMISTRY REVIEW(S)

AF Number

Name and Address of Applicant (City and State)

Smith Kline & French Laboratories
Philadelphia, PA 19101

Original xxxx
Amendment _____
Supplement _____
Resubmission _____
Correspondance _____
Report _____
Other _____

Purpose of Amendment/Supplement

manufacturing information - FPL

Date(s) of Submission(s)

2-19-76

Pharmacological Category

amphetamine

Name of Drug

Benzedrine (amphetamine sulfate)

Dosage Form(s)

tablet

Potency(ies)

5 mg. and 10 mg.

How Dispensed

R_x xxxx

OTC

Packaging/Sterilization

included

Samples

not required

Related IND/NDA/MF

Labeling

satisfactory per medical officer's review of 2-23-76

Biologic Availability

not required in the Federal Register notice

Establishment Inspection

satisfactory per related HFD-322 memo of 1-22-76 based on inspection of 3-14-75

Components, Composition, Manufacturing and Controls

satisfactory

Remarks

approval majarski

ISI

2/25/76

Conclusion

REVIEWER

DATE

CHEMIST'S REVIEW FOR
ABREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Federal Register
Statement Date

ANDA Number
83-900

AF Number

Name and Address of Applicant (City and State)
Smith Kline & French Laboratories
Philadelphia, PA 19101

Original	
Amendment	xxxxxx
Supplement	
Resubmission	
Correspondance	
Report	
Other	xxxxx

Purpose of Amendment/Supplement
decontrolled from 17-072 to 83-900

Date(s) of Submission(s)
2-22,9-17,10-15 1973
7-26,12-10, 1974
10-15-75

Pharmacological Category
amphetamine

Name of Drug
Benzedrine

Dosage Form(s)
tablet

Potency (ies)
amphetamine sulfate
5 and 10 mg.

How Dispensed
Rx xxxxx
OTC

Packaging/Sterilization

Samples

Related IND/ANDA/MF
17-071: spansule

Labeling
requires labeling note : package insert approved by division 5-21-75

Biologic Availability
not required

Establishment Inspection
satisfactory

Components, Composition, Manufacturing and Controls
as per issuing letter

Remarks
inadequate
ma jarski

Conclusion
(IS) 10/28/75

Signature / IEMER DATE