CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

83900

ADMINISTRATIVE DOCUMENTS

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER: 83-900

DATE APPROVAL LETTER ISSUED: FEB 26 1976

TO: Press Relations Staff *(PA-40)*

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

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
- [XX] ABBREVIATED ORIGINAL NDA
- [ ] SUPPLEMENT TO ANDA

CATEGORY
- [XX] 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
- [XX] 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

FORM PREPARED BY

NAME: ajarski — DATE:

FORM APPROVED BY

NAME: jlmeyer — DATE:

Form FD 1642 (4/73) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

Acting Director
Office of Scientific Evaluation

June 18, 1973

Thru: Director
Division of Actions Implementation, DESI

Acting Director
Division of Neuropharmacological Drug Products

Proposal to Transfer Single Entity Amphetamine and Dextroamphitamine NDAs to DESI: ACTION MEMORANDUM

FACTS

We are recommending the transferring of some 27 single entity amphetamine and dextroamphetamine NDAs (List attached) to the Division of Actions Implementation, DESI, since the 2/12/73 Federal Register Announcement (attached) now requires ANDAs for these products. All of these NDAs have been resubmitted since 2/12/73.

It would appear that for consistency of policy DESI should handle all of these products together. DESI now has pending 10-12 of these type products submitted since, 2/12/73, some of which have been submitted by firms that also have different dosage forms now pending in DNDP.

We have talked with Jack Meyer and he is agreeable to such a transfer. The applicants would have to be notified and a new ANDA number assigned to each.

Barrett Scoville, M.D.

Concur_____ Nonconcur_____ Date_____

Prepared By: BD-120, BYERS , 6/18/73,X33810

cc:
BD-100 BD-120 BD-69/Dr.Selfe FT/cld/6/18/73/BD-120/B. BYER ~~GOCKLIn~~
BD-100/Dr.Leong CA-228
BD-120/Dr.Scoville