CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40-361

ADMINISTRATIVE DOCUMENTS

DIVISION REVIEW SUMMARY

ANDA: 40-361

DRUG PRODUCT: Dextroamphetamine Sulfate, USP Tablets

FIRM: Barr Laboratories Inc.

DOSAGE FORM: Tablets

STRENGTH: 20 mg

CGMP STATEMENT/EIR UPDATE STATUS:
EER: ~~Pending~~ Acceptable dated 1/19/01 (GT)

BIO INFORMATION:
The Division of Bioequivalence has found the application to be acceptable. The review was completed on 4/2/99 by M.Makary.

VALIDATION-DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S)
USP product, methods validation not required.

STABILITY-ARE CONTAINERS USED IN THE STUDY IDENTICAL TO THOSE USED IN THE CONTAINER SECTION?

The firm includes a listing of the future testing specifications for the drug product on stability. These are listed below: *(See next page)*

Test	Limit
Description	
Dissolution	in, meets USP
Assay	
*Impurities/Degradation Products	

Water

*Revised upon request

The firm included a summary of 3 months of accelerated data at 40°C/75% RH for lots #8R95204 (5 mg) and #8R95305 (10 mg). Data for both container configurations (100 and 500 fill) were included for the 5 mg strength, and (100 and 1000 fill) for the 10 mg strength. The 500 fill for the 10 mg strength was bracketed. The firm did not submit any room temperature data, but they will test future room temperature stability at 25-30°C, ambient humidity. The firm proposes an 24 month expiration dating period.

Also included is a future stability commitment in accordance with FDA Guidelines.

**The 4/5/00 amendment included stability data (lots 309529001 and 309539001) for the lots manufactured using the / drug substance material). 3 months of accelerated data and 3 months of room temperature was submitted. The tablets were packaged in 100 count botles with metal caps. Data was also provided for the bulk sample The firm has stated that they do not propose to market the product in anything but a 100 count bottle at this time.

LABELING
The labeling review is acceptable as of 8/16/00.

STERILIZATION VALIDATION
NA

SIZE OF DEMONSTRATION BATCH
A description of the manufacturing and processing instructions is included beginning on page 11-00001. The process is a operation and begins with the

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Contain Trade Secret, Commercial/Confidential Information and are not releasable.

1/19/07

**In the 4/5/00 amendment, the firm is seeking approval of the alternate drug substance supplier . In support of this, the firm manufactured two batches (5 and 10 mg) using the material. Although the firm submitted stability data and finished product COAs for the new lots (#309529001 and 309539001).

PROPOSED PRODUCTION BATCH-MANUFACTURING PROCESS THE SAME AS BIO/STABILITY?
Same

RECOMMENDATION: Approve

SIGNATURE: DATE: January 16, 2001

Endorsements: