

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-303/S-001**

**CHEMISTRY REVIEW(S)**

CHEMIST REVIEW  
OF SUPPLEMENT

1. ORGANIZATION: HFD-120  
2. NDA: 21-303  
3. SUPPLEMENT NUMBERS/DATES: SCM-001  
Letter date: October 26, 2001  
Stamp date: October 26, 2001  
4. AMENDMENTS/REPORTS/DATES: N/A  
5. RECEIVED BY CHEMIST: October 30, 2001

6. APPLICANT NAME & ADDRESS

Shire Laboratories, Inc.  
1901 Research Boulevard, Suite 500  
Rockville, MD 20850

7. NAME OF DRUG:

ADDERALL XR CII (extended-release capsule-Mixed salts of a single-Entity Amphetamine Product)

8. NONPROPRIETARY NAME:

(Code Name: SLI 381)

9. CHEMICAL NAME/STRUCTURE:

Amphetamine sulfate USP, Amphetamine aspartate monohydrate, Dextroamphetamine sulfate USP, and Dextroamphetamine saccharate

10. DOSAGE FORM(S):

Capsules

11. POTENCY:

Proposed 5 mg, 15 mg, 25 mg; Approved 10 mg, 20 mg, and 30 mg.

12. PHARMACOLOGICAL CATEGORY:

Treatment of ADHD

13. HOW DISPENSED:

X  (Rx)   (OTC)

14. RECORDS & REPORTS CURRENT:

Yes   No

15. RELATED IND/NDA/DMF:

N/A

**SUPPLEMENT PROVIDES FOR:** This supplement provides for three additional strengths (5 mg, 15 mg, and 25 mg) of ADDERALL-XR capsules.

**Comments:** All three of the formulations included in the original application used the same intermediate pellet components, SLI 381 Immediate-Release (IR) pellets and SLI 381 Delayed-Release (DR) pellets to achieve this two-pulse profile. Two of the three products included in this supplement, SLI 381 Capsules 15 mg and 25 mg, use the same intermediate pellet component as described in the original application. The third finished product SLI 381 Capsule, 5 mg, was developed using the same formulation of SLI DR pellets and

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The use of ~~\_\_\_\_\_~~  
~~\_\_\_\_\_~~  
~~\_\_\_\_\_~~

~~\_\_\_\_\_~~ The new strength capsule meet all regulatory specifications as approved in original NDA 21-303.

**Conclusion:** This supplement may be approved. Please provide the container labels as soon as they become available.

Reviewer's Signature

Acting Team Leader

Christy S. John, Ph.D.

Hasmukh Patel, Ph.D.

DRAFT PORTION OF LETTER ATTACHED: YES \_\_\_\_\_ NO X .

NDA 13-263

HFD-120/CJohn

HFD-120/Division File

HFD-120/HPatel

HFD-120/AHomonnay

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Christy John  
2/22/02 12:39:10 PM  
CHEMIST

Hasmukh Patel  
2/22/02 12:59:10 PM  
CHEMIST

17 Page(s) Withheld

X § 552(b)(4) Trade Secret / Confidential

       § 552(b)(4) Draft Labeling

       § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 1