

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020859

CHEMISTRY REVIEW(S)

M. 112

AUG - 9 1999

DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-859 **CHEM. REVIEW #** 3 **REVIEW DATE:** 8/09/99

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
ORIGINAL	12/30/97	12/30/97	04/15/98 (see CR#1)
AMENDMENT [AC]	10/01/98	10/05/98	10/05/98 (see CR#1)
AMENDMENT [BC]	11/24/98	11/25/98	11/27/98 (see CR#2)
AMENDMENT [BC]	02/17/99	02/19/99	03/15/99 (see CR#2)
AMENDMENT [BC]	02/26/99	02/27/99	03/15/99 (see CR#2)
AMENDMENT [BC]	04/09/99	04/12/99	04/14/99 (see CR#2)
AMENDMENT [BC]*	07/08/99	07/09/99	07/09/99
AMENDMENT [BC]*	07/12/99	07/13/99	07/14/99
AMENDMENT [NC]*	07/10/99	07/14/99	07/14/99
AMENDMENT [NC]*	07/13/99	07/15/99	07/15/99
AMENDMENT [BC]*	07/29/99	07/30/99	08/06/99

* Subject of this review

NAME & ADDRESS OF APPLICANT:

Wyeth-Ayerst Laboratories
P.O. Box 8299
Philadelphia, PA 19101

DRUG PRODUCT NAME

Proprietary:

Nonproprietary/USAN:

Code Name/#:

Chem. Type/Ther. Class:

Sonata (zaleplon) capsules

Zaleplon

Wyeth-Ayerst code designation: ZAL-846
3S

PHARMACOL. CATEGORY/INDICATION:

DOSAGE FORM:

STRENGTHS:

ROUTE OF ADMINISTRATION:

DISPENSED:

Sedative hypnotic

Hard gelatin capsules

5 mg and 10 mg capsules

Oral

Rx OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

See USP Dictionary of USAN and International Drug Names, 1996, page 755.

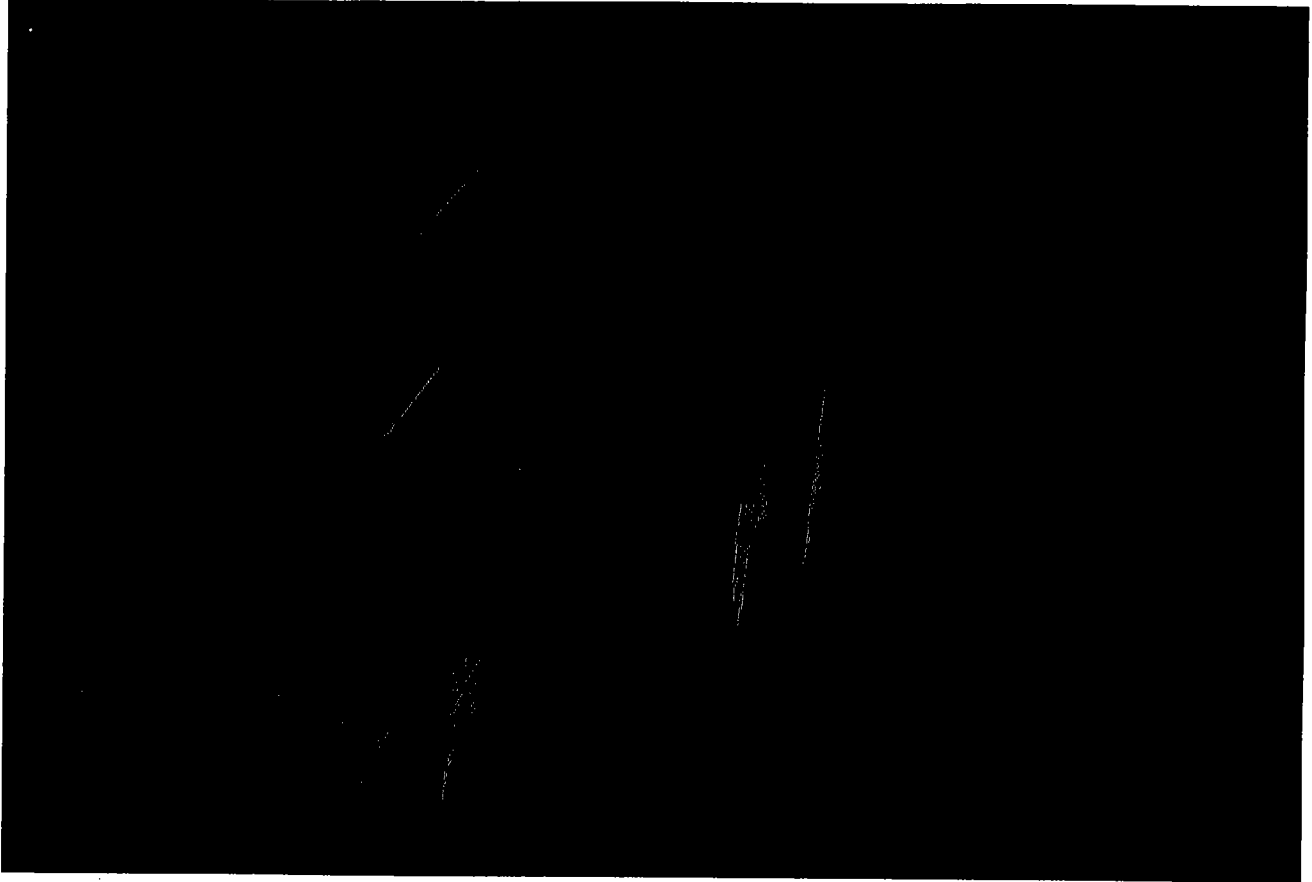
APPEARS THIS WAY ON ORIGINAL

N20859 CR#3

2

SUPPORTING DOCUMENTS:

DMFs:



RELATED DOCUMENTS (if applicable): IND [REDACTED]

CONSULTS:

EER: Acceptable. [REDACTED]

REMARKS/COMMENTS: The deficiencies in drug substance, drug product and container closure have been satisfactorily addressed by the applicant. The applicant's proposed 36 month shelf life for the drug product is acceptable. [REDACTED]

[REDACTED]

APPEARS THIS WAY ON ORIGINAL [REDACTED]

N20859 CR#3

3

CONCLUSIONS & RECOMMENDATIONS: From a CMC perspective, recommend APPROVAL (AP). 

/s/ 

8/09/99
Rik Lostritto, Ph.D. Review Chemist

/s/ 

8/19/99
Robert Seevers, Ph.D. Chemistry Team Leader

R/D Init by: _____

filename: C:N20859.r3

cc:

Org. NDA 20-859
HFD-120/Division File
HFD-120/RLostritto
HFD-120/RSeevers
HFD-120/MMille

APPROVAL


APPEARS THIS WAY ON ORIGINAL

Mille

JUN 23 1999

DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-859 **CHEM. REVIEW #** 2 **REVIEW DATE:** 6/23/99

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
ORIGINAL	12/30/97	12/30/97	04/15/98 (see CR#1)
AMENDMENT [AC]	10/01/98	10/05/98	10/05/98 (see CR#1)
AMENDMENT [BC]*	11/24/98	11/25/98	11/27/98
AMENDMENT [BC]*	02/17/99	02/19/99	03/15/99
AMENDMENT [BC]*	02/26/99	02/27/99	03/15/99

* Subject of this review

NAME & ADDRESS OF APPLICANT:

Wyeth-Ayerst Laboratories
P.O. Box 8299
Philadelphia, PA 19101

DRUG PRODUCT NAME

Proprietary:

Sonata (zaleplon) capsules

Nonproprietary/USAN:

Zaleplon

Code Name/#:

Wyeth-Ayerst code designation:

ZAL-846

Chem. Type/Ther. Class:

3S

PHARMACOL. CATEGORY/INDICATION:

Sedative hypnotic

DOSAGE FORM:

Hard gelatin capsules

STRENGTHS:

5 mg and 10 mg capsules

ROUTE OF ADMINISTRATION:

Oral

DISPENSED:

Rx OTC

CHEMICAL NAME. STRUCTURAL FORMULA. MOLECULAR FORMULA. MOLECULAR WEIGHT:

See USP Dictionary of USAN and International Drug Names, 1996, page 755.

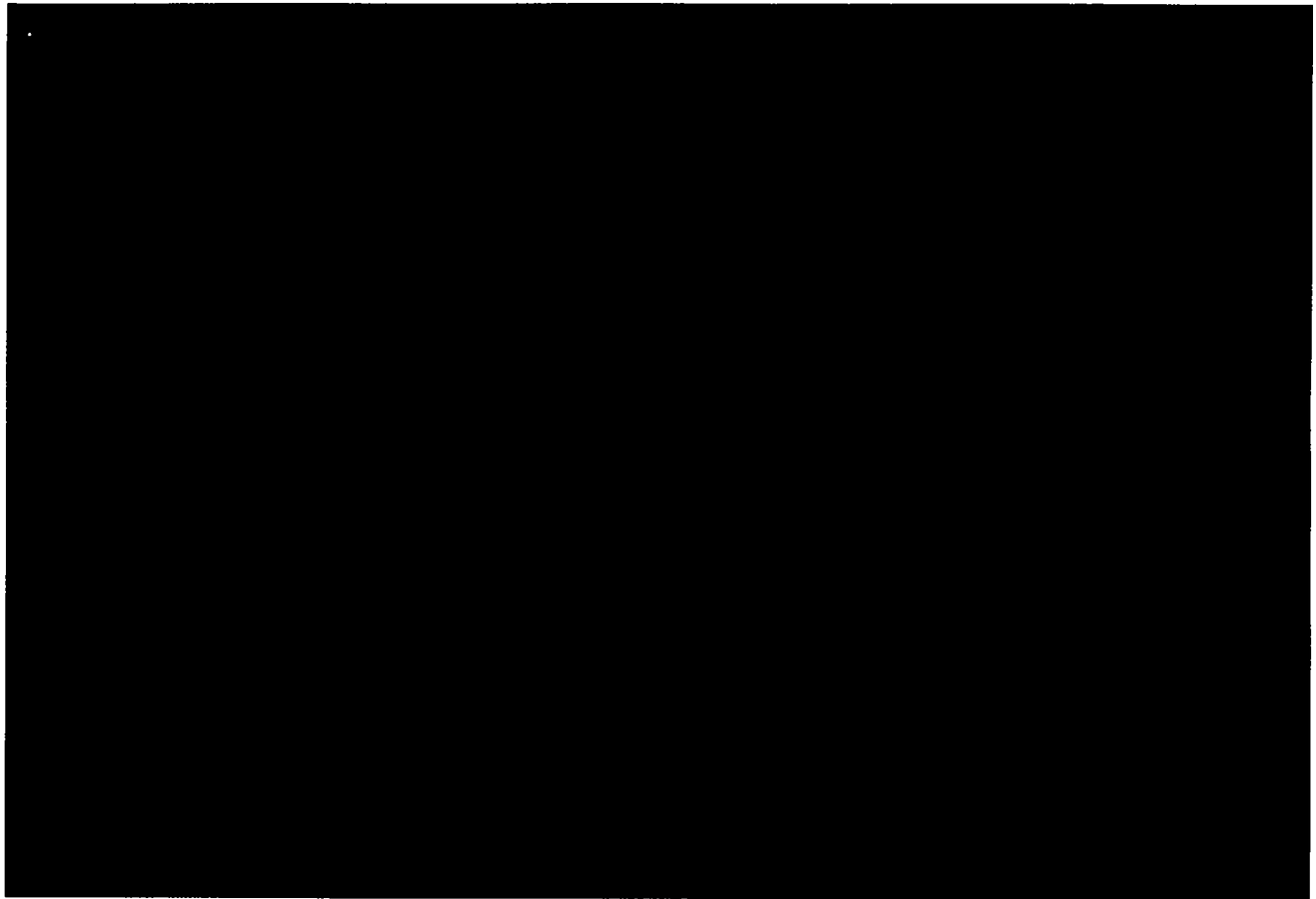
APPEARS THIS WAY ON ORIGINAL

N20859 CR#2

2

SUPPORTING DOCUMENTS:

DMFs:



RELATED DOCUMENTS (if applicable): IND [REDACTED]

CONSULTS:

EER: Acceptable. Report attached in Appendix to CR#1.



N20859 CR#2

3

CONCLUSIONS & RECOMMENDATIONS:

Approvable until the deficiencies noted herein are adequately responded to.

/S/ [Redacted]

6/23/99

Rik Lostritto, Ph.D. Review Chemist

/S/ [Redacted]

6/23/99

Robert Seevers, Ph.D. Chemistry Team Leader

R/D Init by: _____

filename: C:N20859.r2

cc:

Org. NDA 20-859

HFD-120/Division File

HFD-120/RLostritto

HFD-120/RSeevers

HFD-120/MMille

APPEARS THIS WAY ON ORIGINAL

DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-859 **CHEM. REVIEW #** 1 **REVIEW DATE:** 10/05/98

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL*	12/30/97	12/30/97	04/15/98
AMENDMENT (AC)*	10/01/98	10/05/98	10/05/98

* Subject of this review

NAME & ADDRESS OF APPLICANT:

Wyeth-Ayerst Laboratories
P.O. Box 8299
Philadelphia, PA 19101

DRUG PRODUCT NAME

Proprietary:
Nonproprietary/USAN:
Code Name/#:
Chem. Type/Ther. Class:

Sonata (zaleplon) capsules
Zaleplon
Wyeth-Ayerst code designation: ZAL-846
3S

PHARMACOL. CATEGORY/INDICATION:

Sedative hypnotic

DOSAGE FORM:

Hard gelatin capsules

STRENGTHS:

5 mg and 10 mg capsules

ROUTE OF ADMINISTRATION:

Oral

DISPENSED:

Rx OTC

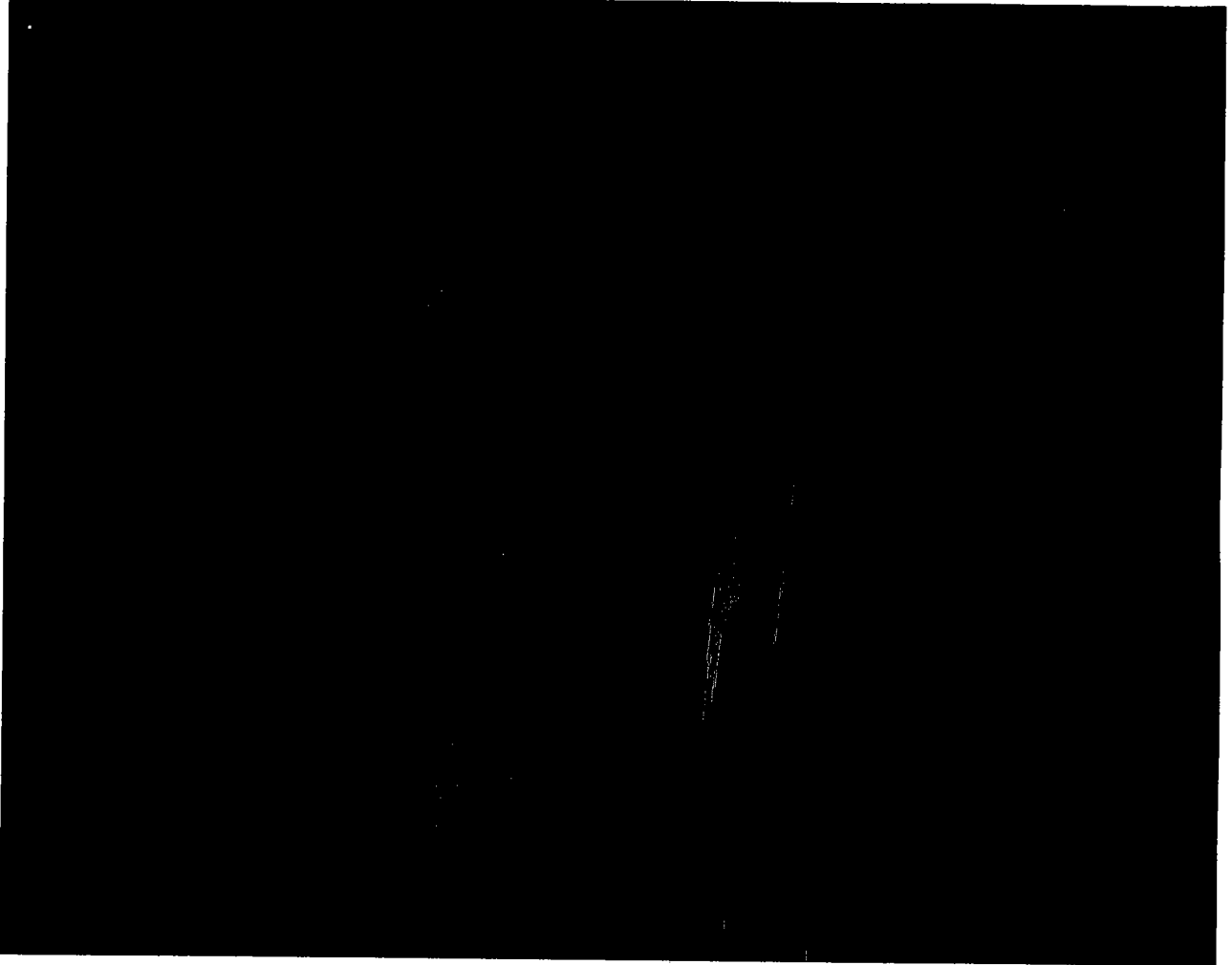
CHEMICAL NAME. STRUCTURAL FORMULA. MOLECULAR FORMULA. MOLECULAR WEIGHT:

See USP Dictionary of USAN and International Drug Names, 1996, page 755.

APPEARS THIS WAY ON ORIGINAL

SUPPORTING DOCUMENTS:

DMFs:



RELATED DOCUMENTS (if applicable): IND [redacted]

CONSULTS:

EER: Acceptable. [redacted]



CONCLUSIONS & RECOMMENDATIONS:

Not approvable until the deficiencies noted are adequately responded to.

.. ISI
[Redacted Signature]

10/05/98

Rik Lostritto, Ph.D. Review Chemist

ISI
[Redacted Signature]

10/15/98

Robert Seevers, Rh.D. Chemistry Team Leader

R/D Init by: _____

filename: C:20859r1

cc:

Org. NDA 20-859

HFD-120/Division File

HFD-120/RLostritto

HFD-120/RSeevers

HFD-120/TWheelous ← APPEARS THIS WAY ON ORIGINAL

[Redacted]