

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-434

CHEMISTRY REVIEW(S)

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Abbreviated New Drug Application Review

1. CHEMISTRY REVIEW NO. 3
2. ANDA # 75-434
3. NAME AND ADDRESS OF APPLICANT
Eon Labs Manufacturing, Inc.
Attention: Blessy Johns
227-15 North Conduit Avenue
Laurelton, New York 11413
4. LEGAL BASIS FOR SUBMISSION
All patents and exclusivities for the drug substance, drug product, dosing schedule, use, and indications have expired.

ANDA #18-932 REVIA approved on November 20, 1984
Du Pont Pharmaceuticals.
5. SUPPLEMENT(s)
N/A
6. PROPRIETARY NAME
NA
7. NONPROPRIETARY NAME
Naltrexone Hydrochloride Tablets, USP
8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A
9. AMENDMENTS AND OTHER DATES:
Firm:
August 6, 1998 - Original submission
November 6, 1998 - Bioequivalence Telephone Amendment
April 23, 1999 - Major Amendment CMC and Labeling
November 12, 1999 - Minor Amendment CMC
December 6, 1999 - Minor Amendment Labeling
10. PHARMACOLOGICAL CATEGORY
Narcotic antagonist
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)
NDA# 18-932
13. DOSAGE FORM
Tablet
14. POTENCY
50 mg

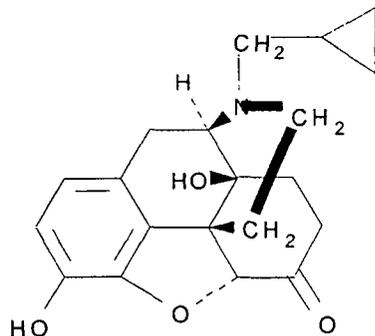
17-(Cyclopropylmethyl)-4,5-epoxy-3,14-dihydroxymorphinan-6-one Hydrochloride Chem.

15. CHEMICAL NAME AND STRUCTURE

Chemical name:

17-(Cyclopropylmethyl)-4,5 α -epoxy-3,14-dihydroxymorphinan-6-one hydrochloride.

Chemical Formula	Molecular weight	CAS Number
C ₂₀ H ₂₃ NO ₄ · HCl	MW= 377.87	16676-29-2



· HCl

STRUCTURAL FORMULA:
Naltrexone Hydrochloride

17-(Cyclopropylmethyl)-4,5 α -epoxy-3,14-dihydroxymorphinan-6-one hydrochloride. CAS [16676-29-2]

16. RECORDS AND REPORTS

September 1, 1998 - Letter for date acceptable filing
August 11, 1998.

November 6, 1998 - Bioequivalence Review #1 (C. Kim)

November 12, 1998 - Labeling Review #1 (A. Vezza)

March 8, 1999 - Chemistry Review #1 (S. Basaran)

April 2, 1999 - Major CMC and Labeling deficiencies
forwarded to the applicant.

May 7, 1999 - Labeling Review #2 (A. Vezza)

October 29, 1999 - Chemistry Review #2 (M. Piñeiro-Sánchez)
December 16, 1999 - Chemistry Review #3 (M. Piñeiro-Sánchez)

17. COMMENTS

No chemistry, bioequivalence, labeling, or method validation issues remain.

18. CONCLUSIONS AND RECOMMENDATIONS

The application is recommended for approval.

19. REVIEWER:

Mayra Piñeiro-Sánchez, Ph.D.

DATE COMPLETED:

December 16, 1999

Final - February 4, 2000

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Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

John Rev 3

12/16/99