

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**75-232**

**CHEMISTRY REVIEW(S)**

1. CHEMIST'S REVIEW NO. 4
2. ANDA # 75-232
3. NAME AND ADDRESS OF APPLICANT  
L. Perrigo Co.  
Attention: Mr. Brian R. Schuster  
117 Water Street  
Allegan, MI 49010
4. LEGAL BASIS FOR ANDA SUBMISSION  
To the best of the applicant's knowledge, there are no patents that claim the RLD (page 10). There is no marketing exclusivity information either for the RLD.
5. PROPRIETARY NAME      6. NONPROPRIETARY NAME  
Loperamide Hydrochloride, USP
9. AMENDMENTS AND OTHER DATES:  
**FIRM**  
February 23, 1998      Original Submission  
July 9, 1998              Bio amendment  
January 14, 1999        Major amendment  
September 23, 1999     Response to facsimile deficiencies  
November 18, 1999      Response to facsimile deficiencies  
December 30, 1999      Telephone Amendment  
  
**FDA**  
April 2, 1998             Acceptable for filing on 3/2/98  
June 2, 1998             Bio review  
June 9, 1998             Bio deficiency letter  
September 29, 1998     Chemistry & Label deficiency fax  
October 27, 1998        Acceptable Bio review  
July 16, 1999            Facsimile deficiencies by Chemistry  
November 16, 1999      Facsimile deficiencies by Chemistry
10. PHARMACOLOGICAL CATEGORY  
Antidiarrheal
11. Rx or OTC  
OTC
12. RELATED DMFs Nos.

**ANDA 74-194-Approved for Perrigo for 2 mg caplets**

13. DOSAGE FORM  
Tablets
14. POTENCY  
2 mg

15. CHEMICAL NAME AND STRUCTURE  
1-Piperidinebutanamide, 4-(4-chlorophenyl)-4-hydroxy-N,N-dimethyl-alpha,alpha-diphenyl-, monohydrochloride
16. RECORDS AND REPORTS  
N/A
17. COMMENT  
No outstanding chemistry deficiencies remain.
18. CONCLUSION AND RECOMMENDATIONS  
ANDA recommended for approval.
19. REVIEWER: Radhika Rajagopalan, Ph.D., DATE COMPLETED: November 30, 1999  
January 3, 1999

*Radhika Rajagopalan* 1/3/00

Page(s) 13

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

Chem Rev 4

11/30/99