

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**20-776**

**CHEMISTRY REVIEW(S)**

**Division of Anti-inflammatory, Analgesic and Ophthalmic Drugs  
HFD-550**

**Review of Chemistry, Manufacturing, and Controls**

**NDA #:** 20-776

**DATE REVIEWED:** 14-Jul-2000

**REVIEW #** 2

**REVIEWER:** Rao Puttagunta

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
ORIGINAL	19-MAY-1997	20-MAY-1997	22-MAY-1997
Amendment (RS)	21-JAN-2000	24-JAN-2000	01-MAR-2000

**NAME & ADDRESS OF APPLICANT:**

G.D. Searl & Co.  
4901 Searl Parkway  
Skokie, IL 60077

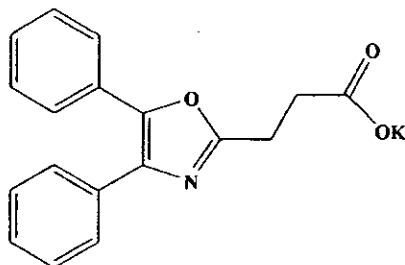
**DRUG PRODUCT NAME**

Proprietary: Benilas  
Established: Oxaprozin Potassium  
Code Name/#: SC-62845; CAS-174064-08-5  
Chem.Type/Ther.Class: 2S

**PHARMACOL. CATEGORY:** NSAID  
**DOSAGE FORM:** Tablet  
**STRENGTHS:** 600 mg  
**ROUTE OF ADMINISTRATION:** Oral  
**DISPENSED:**  Rx  OTC  
**SPECIAL PRODCUTS:**  Yes  No

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

4,5-Diphenyl-2-oxazolepropanoic acid, potassium salt  
N-(2-oxo-1,2-diphenylethyl)-succinamic acid, potassium salt  
 $C_{18}H_{14}KNO_3$ , mol.wt. 331.40



Lutwak  
550

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

**DATE:** April 28, 1998  
**FROM:** Charlotte A. Yaciw, HFD-550/830  
**TO:** Vickey Lutwak, Project Manager, HFD-550  
**THROUGH:** Hasmukh Patel, Chemistry Team Leader, HFD-550  
**SUBJECT:** NDA 20-776, Amendment Dated 4/<sup>21</sup>12/98

MSB  
4-28-98

This amendment contains revised draft container labeling incorporating the new tradename, Benilas. They also include the currently recommended storage statement and the new "R only" designation. These labels are acceptable.

*Charlotte A. Yaciw*

Charlotte A. Yaciw

cc:  
NDA 20-776  
HFD-550 Division File  
HFD-550/PM/Lutwak  
HFD-550/Chem/Yaciw  
HFD-830/DNDCIII/Chen

Document ID: n20776la.wpd

**Division of Anti-inflammatory, Analgesic and  
Ophthalmic Drug Products  
Review of Chemistry, Manufacturing, and Controls**

**NDA #:** 20-776

**REVIEW # 1**

**DATE REVIEWED:** 12/10/97

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
SUBMISSION	5-19-97	5-20-97	5-22-97
AMENDMENT	6-6-97	6-9-97	6-13-97
AMENDMENT	6-25-97	6-26-97	6-30-97
AMENDMENT	9-30-97	10-1-97	10-3-97
AMENDMENT	10-7-97	10-9-97	10-16-97
T-CON	11-13-97 (copy attached)		
AMENDMENT	11-24-97	11-26-97	12-3-97

**NAME & ADDRESS OF APPLICANT:** G. D. Searle & Co.  
4901 Searle Parkway  
Skokie, Illinois 60077

**DRUG PRODUCT NAME**

**Proprietary:** To be determined  
**Established:** Oxaprozin potassium  
**Code Name/#:** SC-62845; CAS-174064-08-5  
**Chem. Type/Ther. Class:** 2S

**PHARMACOL. CATEGORY:**

NSAID

**DOSAGE FORM:**

Tablet

**STRENGTHS:**

600 mg

**ROUTE OF ADMINISTRATION:**

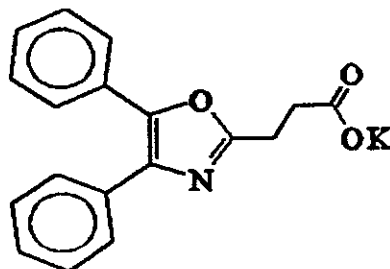
oral

**DISPENSED:**

Rx  OTC

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

4,5-Diphenyl-2-oxazolepropanoic acid, potassium salt  
N-(2-oxo-1,2-diphenylethyl)-succinamic acid, potassium salt  
 $C_{18}H_{14}KNO_3$  331.40



**OXAPROZIN POTASSIUM**

22 Page(s) Withheld

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

§ 552(b)(5) Deliberative Process

§ 552(b)(5) Draft Labeling

FDA CDER EES  
ESTABLISHMENT EVALUATION REQUEST  
SUMMARY REPORT

Application: NDA 20776/000	Priority: 2S	Org Code: 550
Stamp: 20-MAY-1997 Regulatory Due: 24-JUL-2000	Action Goal:	District Goal: 01-OCT-1997
Applicant: SEARLE 4901 SEARLE PKY SKOKIE, IL 60077	Brand Name: BENILAS (OXAPROZIN POTASSIUM) 600MG TABS	Established Name:
	Generic Name: OXAPROZIN POTASSIUM	Dosage Form: TAB (TABLET)
	Strength: 600 MG	
FDA Contacts: S. SCHMIDT (HFD-550)	301-827-2090	, Project Manager
R. PUTTAGUNTA (HFD-830)	301-827-0968	, Review Chemist
M. ZARIFA (HFD-120)	301-594-2850	, Team Leader

## Overall Recommendation:

**ACCEPTABLE on 06-MAR-2000 by J. D AMBROGIO (HFD-324) 301-827-0062**  
**ACCEPTABLE on 30-SEP-1997 by M. EGAS (HFD-322) 301-594-0095**

Establishment: \_\_\_\_\_

DMF No:

AADA No:

Profile: CTL OAI Status: NONE  
Last Milestone: OC RECOMMENDATION  
Milestone Date: 02-MAR-2000  
Decision: ACCEPTABLE  
Reason: BASED ON PROFILE

Responsibilities: \_\_\_\_\_

Establishment: 2623450  
GD SEARLE AND CO  
99 JARDINES STREET  
CAGUAS, PR 00725

DMF No:

AADA No:

Profile: TCM OAI Status: NONE  
Last Milestone: OC RECOMMENDATION  
Milestone Date: 06-MAR-2000  
Decision: ACCEPTABLE  
Reason: DISTRICT RECOMMENDATION

Responsibilities: FINISHED DOSAGE  
MANUFACTURER  
FINISHED DOSAGE PACKAGER  
FINISHED DOSAGE RELEASE  
TESTER

Establishment: 1035462  
SEARLE CHEMICALS INC SUB GD SE  
1750 LOVERS LANE  
AUGUSTA, GA 30901

DMF No:

AADA No:

Profile: CSN OAI Status: NONE  
Last Milestone: OC RECOMMENDATION

Responsibilities: DRUG SUBSTANCE  
MANUFACTURER

FDA CDER EES  
ESTABLISHMENT EVALUATION REQUEST  
SUMMARY REPORT

DRUG SUBSTANCE RELEASE  
TESTER

Milestone Date: 02-MAR-2000  
Decision: ACCEPTABLE  
Reason: BASED ON FILE REVIEW  
BASED ON PROFILE

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