020776_Original Approval_ Package. PDF

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-776

Trade Name: Daypro ALTA

Generic Name: Oxaprozin Potassium Tablets

Sponsor: Pharmacia Corporation

Approval Date: October 17, 2002

Indications: Daypro is indicated for relief of the signs and symptoms of osteoarthritis and rheumatoid arthritis

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-776

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	**X**
Approvable Letter(s)	**X**
Final Printed Labeling	**X**
Medical Review(s)	**X**
Chemistry Review(s)	**X**
EA/FONSI	
Pharmacology Review(s)	**X**
Statistical Review(s)	**X**
Microbiology Review(s)	**X**
Clinical Pharmacology/ Biopharmaceutics Review(s)	**X**
Administrative Document(s) and Correspondence	**X**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-776

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20776

Pharmacia Corporation
Attention: Susan Tegtmeyer
Manager, Global Regulatory Affairs
4901 Searle Parkway
Skokie, Illinois, 60077

Dear Ms. Tegtmeyer:

Please refer to your new drug application (NDA) dated May 19, 1997, received May 20, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Daypro ALTA (oxaprozin potassium) 600mg tablets and subsequent submissions dated April 21, 1998, March 9, 2000, and June 11, 2001.

We acknowledge receipt of your submissions dated April 19, June 14, October 1 and 11, 2002.

This new drug application provides for the use of Daypro ALTA (oxaprozin potassium) 600mg tablets for relief of the signs and symptoms of osteoarthritis and rheumatoid arthritis.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text attached to the end of this letter. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted on October 11, 2002, immediate container and carton labels and the labels for hospital unit dose blister submitted on June 14, 2002). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20776." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Nancy Halonen, Project Manager, at 301-827-2019.

Sincerely,

{See appended electronic signature page}

Lee S. Simon, M.D.
Director
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Lee Simon
10/17/02 05:24:46 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-776

APPROVABLE LETTER

HFD-550/S. Schmidt

NDA 20-776

G. D. Searle and Company
Attention: Daryl DeKarske, M.P.H.
Senior Associate, Worldwide Regulatory Affairs
4901 Searle Parkway
Skokie, Illnois 60077

JUL 21 2000

Dear Mr. DeKarske:

Please refer to your new drug application (NDA) dated January 21, 2000, received January 24, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Benilas (oxaprozin potassium), 600 mg Tablets.

We acknowledge receipt of your submissions dated March 9(2) and 22, May 5 and June 6, 2000. Your submission of January 21, 2000, constituted a complete response to our May 20, 1999, action letter. This submission provides additional information to support an — indication.

We have completed the review of this application, as amended, and it is approvable. There is adequate information, as submitted in your May 19, 1997 submission, to support the proposed osteoarthritis and rheumatoid arthritis indications. However, there is inadequate information as submitted in the January 21, 2000 amendment to support the proposed — indication for the following reason:

/

In addition, it will be necessary for you to submit draft labeling consistent with the enclosed labeling.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

Under 21 CFR 314.50(d)(5)(vi)(*b*), we request that you update your NDA by submitting all safety information you now have regarding your new drug. Please provide updated information as listed below. The update should cover all studies and uses of the drug including: (1) those involving indications not being sought in the present submission, (2) other dosage forms, and (3) other dose levels, etc.

1. Retabulation of all safety data including results of trials that were still ongoing at the time of NDA submission. The tabulation can take the same form as in your initial submission. Tables comparing adverse reactions at the time the NDA was submitted versus now will certainly facilitate review.

certainly facilitate review.

2. Retabulation of drop-outs with new drop-outs identified. Discuss, if appropriate.

3. Details of any significant changes or findings.

4. Summary of worldwide experience on the safety of this drug.

5. Case report forms for each patient who died during a clinical study or who did not complete a study because of an adverse event.

6. English translations of any approved foreign labeling not previously submitted.

7. Information suggesting a substantial difference in the rate of occurrence of common, but less serious, adverse events.

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of any such action FDA may proceed to withdraw the application. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d) of the new drug regulations, you may request an informal meeting or telephone conference with this division to discuss what further steps need to be taken before the application may be approved.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, call Sharon Schmidt, M.S., Project Manager, at (301) 827-2536.

Sincerely,

Karen Midthun 7-21-00

Karen Midthun, M.D.
Director
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Archival NDA 20-776
HFD-550/Div. Files
HFD-550/S.Schmidt/L.Vaccari
HFD-550/C.Fang/M.O./K.Midthun/Div.Dir./R.Puttagunta/Chemist/M.Zarifa/ChemTL/L.Lu/Stat./S. Lin/Stat.T.L.
HFD-002/ORM
HFD-105/ADRA
HFD-830/DNDC Division Director
DISTRICT OFFICE

Drafted by: sas/July 17, 2000
Initialed by: L.Vaccari/7-21-00
C.Fang/7-21-00
K.Midthun/7-21-00
R.Pattagunta
M.Zarifa/7-21-00
L.Lu
StanLin/

Drafted by: sas/July 20, 2000
Initialed by:
final:
filename: N20776NA.700

APPROVABLE (AE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-776

MAY 20 1998

G. D. Searle & Co.
Attention: Winifred M. Begley
Director, Regulatory Affairs
4901 Searle Parkway
Skokie, IL 60077

Dear Ms. Begley:

Please refer to your May 19, 1997, new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Benilas (oxaprozin potassium tablets), 600 mg.

We acknowledge receipt of your submissions dated June 6, 9, 20, 25, and 27; July 3; August 13; September 2, 15, 19, and 30; October 7 (two), 21, 28, and 30; November 24, and December 8 and 10, 1997; January 20; February 13; March 9; and April 21, 1998.

We have completed the review of this application as submitted with draft labeling, and it is approvable. There is adequate information to support the proposed osteoarthritis and rheumatoid arthritis indications. However, there is inadequate information to support the proposed — indication for the following reason:

Before this application may be approved, it will be necessary for you to submit in draft or mock-up form labeling consistent with the enclosed.

Under 21 CFR 314.50(d)(5)(vi)(*b*), we request that you update your NDA by submitting all safety information you now have regarding your new drug.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed material should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising,
and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of such action FDA may take action to withdraw the application.

Under 21 CFR 314.102(d) of the new drug regulations, you may request an informal or telephone conference with the Division to discuss what further steps need to be taken before the application may be approved.

The drug may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, please contact Victoria Lutwak, Project Manager, at (301) 827-2090.

Sincerely,

/S/

John Hyde, Ph.D., M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic, and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure: Draft Labeling