

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-341**

**APPROVAL LETTER**



NDA 21-341

G.D. Searle & Co  
Attention: Peter L. East  
Associate Director, Regulatory Affairs  
4901 Searle Parkway  
Skokie, Illinois 60077

Dear Mr. East:

Please refer to your new drug application (NDA) dated January 16, 2001, received January 16, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Bextra (valdecoxib) 10 mg and 20 mg Tablets.

We acknowledge receipt of your submissions dated March 27, April 10, April 18, April 23, May 16, June 19, June 22, June 29, July 6, August 2, August 13, August 16, August 24, August 31, September 13, September 27, October 2, October 17, October 26, October 29, November 2, November 9, 2001.

This new drug application provides for the use of Bextra (valdecoxib) for the relief of signs and symptoms of osteoarthritis and adult rheumatoid arthritis and for the treatment of primary dysmenorrhea.

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 enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). 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 21-341." Approval of this submission by FDA is not required before the labeling is used. Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). We are waiving the pediatric study requirements for this action on this application.

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 send one copy to the Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products 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.

However, we find the following information is inadequate to establish safety and efficacy. Therefore, this portion of the application is not approvable under section 505 (d) of the Act and 21 CFR 314.125(b). The deficiencies are summarized as follows.

1. Safety in the management of acute pain

[REDACTED]

2. Safety and efficacy in the prevention of acute pain in adults

[REDACTED]

3. Safety and efficacy for \_\_\_\_\_

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

If you chose to pursue these indications, the submission will be assigned a new NDA number for administrative purposes and be treated as a resubmission with a goal date of six months.

If you have any questions, call Carmen DeBellas, Chief, Project Management Staff, at (301) 827-2090.

Sincerely yours,

*{See appended electronic signature page}*

Jonca Bull, M.D.  
Acting Director  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research

Enclosure