CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: NDA 20-998

Trade Name: CELEBREX

Generic Name:(celecoxib)

Sponsor: G.D. Searle

Approval Date: December 31, 1998

Indication: Provides for the use of CELEBREX (celecoxib capsules) 100mg and 200 mg for the signs and symptoms of osteoarthritis and rheumatoid arthritis.

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APPLICATION: NDA 20-998

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	Included	Pending Completion	Not Prepared	Not Required
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Final Printed Labeling		X		
Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI	X			
Pharmacology Review(s)	X			
Statistical Review(s)	X			
Microbiology Review(s)			X	
Clinical Pharmacology Biopharmaceutics Review(s)	X			
Bioequivalence Review(s)			X	
Administrative Document(s)	X			
Correspondence	X			

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Application Number:NDA 20-998

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-998

DEC 31 1998

G.D. Searle
Attention: Winifred Begley
Director Regulatory Affairs
4901 Searle Parkway
Skokie, Illinois 60077

Dear Ms. Begley:

Please refer to your new drug application (NDA) dated June 29, 1998, received June 30, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CELEBREX (celecoxib capsules) 100mg and 200 mg.

We acknowledge receipt of your submissions dated June 29 (two); July 6, 7, 14, 16, 21 (two), 22, and 30 (three); August 4 (two), 7 (three), 10, 17, 21, 24 (two), and 27 (two); September 2 (two), 3 (two), 11, 17 (four), 18, 24 (three), 25, and 28 (two); October 1 (three), 2, 5 (two), 7, 8 (two), 13, 14 (three), 15, 16 (five), 20 (two), 21, 23 (four), 26 (three), 27 (three), 28 (four), and 30 (three); November 2, 3, 4, 5, 6 (two), 10, 11 (two), 12, 16 (two), 19 (two), 23 (two), 24, and 25; December 3, 8, 9 (two), 10 (two), 16, 18, 21, 24, and 29; and correspondence via facsimile transmission dated December 29, 1998.

The user fee goal date for this application is December 31, 1998.

This new drug application provides for the use of CELEBREX (celecoxib capsules) 100mg and 200 mg for 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 submitted labeling (package insert submitted December 29, 1998) with the revisions incorporated in the enclosed label text. Accordingly, the application is approved effective on the date of this letter.

These revisions are terms of the NDA approval. Marketing the product before making the revisions, exactly as requested, in the product's final printed label (FPL) may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case 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 20998." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitment specified in your submission dated December 29, 1998.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

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

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.

Please note that any advertising and/or promotional activity of this product will be considered false and/or misleading under Section 502 of the Act if it presents suggestions or representations that COX-2 selectivity confers on the product any claims of safety beyond what has been demonstrated in clinical studies and presented in the approved labeling. Additionally, promotional activities that make or imply comparative claims about the frequency of clinically serious GI events compared to groups of NSAIDs or specific NSAIDs will be considered false and/or misleading without differences having been demonstrated in adequate, well-controlled studies. Finally, any promotional use of the endoscopic data without the qualifying explanations of that data found in the approved labeling (paragraph beginning on line 251 in the enclosed label text) will be considered false and/or misleading. If you have any questions or concerns about this matter please contact the Center for Drug Evaluation and Research's Division of Drug Marketing, Advertising and Communications.

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-40
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, contact Victoria Lutwak, Project Manager, at (301) 827-2090.

Sincerely,

Robert J DeLap 12/31/1998

Robert DeLap, M.D., Ph.D.
Director
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

cc:
Archival NDA 20-998
HFD-550/Div. Files
HFD-550/V.Lutwak
HFD-550/Medical/Hyde/Witter/Averbuch/Villalba
HFD-550/Pharmacology/Weir/Yang
HFD-830/Chemistry/Patel/Bhavnagri
HFD-725/Statistics/Lin/Lu/Gao/Patrician/Thompson
HFD-880/Bashaw/Lee
HFD-180/Talarico/Gallo-Torres/Goldkind
HFD-110/Chen/Throckmorton
HF-2/MedWatch (with labeling)
HFD-002/ORM (with labeling)
HFD-105/ADRA (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-21/ACS (with labeling) - for drug discussed at advisory committee meeting.
HFD-95/DDMS (with labeling)
HFD-830/DNDC Division Director
DISTRICT OFFICE

Drafted by: vl/December 8, 1998
Initialed by:
final:
filename: 981208AP.WPD

APPROVAL (AP) (with Phase 4 Commitments)

FINAL PRINTED LABELING HAS NOT BEEN SUBMITTED TO THE FDA

DRAFT LABELING IS **NO LONGER** BEING SUPPLIED SO AS TO ENSURE ONLY CORRECT AND CURRENT INFORMATION IS DISSEMINATED TO THE PUBLIC.

THIS SECTION WAS DETERMINED **NOT** TO BE RELEASABLE

64 pages