CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20998/S007

CHEMISTRY REVIEW(S)

DIVISION OF ONCOLOGY DRUG PRODUCTS
Original NDA Review of Chemistry, Manufacturing, and Controls

NDA #: 21-156	CHEMISTRY. REVIEW #:	1	REVIEW DATE: December 20, 1999
SUBMISSION TYPE	DOC. DATE	CDER DATE	
Original	June 24, 1999	June 25, 1999	
Amendment	December 16, 1999	December 16, 1999	

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

DRUG PRODUCT NAME:

Proprietary:	Celebrex™ Capsules
Nonproprietary/USAN:	Celecoxib
Chem. Type/Ther. Class:	1P

PHARMACOL. CATEGORY/INDICATION: For the reduction and regression of adenomatous colorectal polyps in Familial Adenomatous Polyposis patients

DOSAGE FORM: Oral Capsule

STRENGTHS: 200mg/capsule

ROUTE OF ADMINISTRATION: Oral

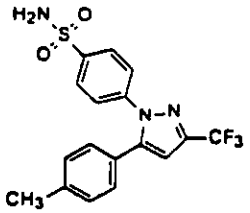
DISPENSED: _x_ Rx ____ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA(M.F.), MOLECULAR WEIGHT(M.W.):

CAS Name: 4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide

M.F.: $C_{17}H_{14}F_3N_3O_2S$

M.W.: 381.38



Celecoxib

CONSULTS: Not applicable.

REMARKS/COMMENTS:

NDA 21-156 efficacy supplement to NDA 20-998 is submitted. The cross-referenced NDA 20-988 was approved on 12/31/98 for the acute or chronic use in the treatment of the signs and symptoms of osteoarthritis and rheumatoid arthritis in adults. Approved strengths are 100mg and 200mg per capsule.

CONCLUSIONS & RECOMMENDATIONS:

No CMC review is required because of efficacy supplement except an environmental assessment. The applicant requested a categorical exclusion from the preparation of the environmental assessment under the provisions of 21CFR 25.31(a) concerning this NDA 21-156. For justification, it is stated that the total planned production of celecoxib is expected to remain within the marketing projections made in the original environmental assessment in the NDA 20-988 application. No increase in the production of celecoxib is expected due to approval of this efficacy supplement. The exemption request for the preparation of the environmental assessment is granted. Adequate.

/S/

Sung K. Kim, Ph.D.,
Review Chemist, HFD-150

cc:
Orig. NDA 21-156
HFD-150/Division File
HFD-150/PZimmerman
HFD-150/SKim
HFD-150/RWood
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