

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-998/s-009

PHARMACOLOGY REVIEW(S)

REVIEW NOT
NEEDED FOR THIS
RESUBMISSION-
SEE ORIGINAL sNDA ACTION
PACKAGE for ORIGINAL
REVIEWS
(AE on 4-12-01)

**DIVISION OF ANTI-INFLAMMATORY, ANALGESIC AND OPHTHALMOLOGIC
DRUG PRODUCTS**

PHARMACOLOGY AND TOXICOLOGY REVIEW

NDA 20-998/S-009

DRUG: Celecoxib; Celebrex™; SC-58635

SPONSOR: G.D. Searle & Co.
4901 Searle Parkway
Skokie, IL 60077

SUBMISSION DATE: June 12, 2000

TYPE OF SUBMISSION: Labeling Supplement

DATE COMPLETED: April 12, 2001

REVIEWER: W. C. Josie Yang, Ph.D.

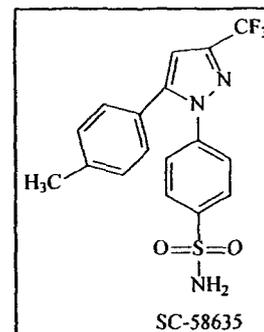
DATE RECEIVED IN HFD-550: June 14, 2000

USER FEE DUE DATE: April 14, 2001

DRUG CATEGORY: Nonsteroidal Anti-inflammatory & Analgesic
[Inhibitor of Cyclooxygenase 2 (COX-2)]

FORMULA: 4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl] benzenesulfonamide (C₁₇H₁₄F₃N₃O₂S);
M.W.: 381.38

INGREDIENTS	QUANTITIES (MG)		FUNCTION
	100 mg Capsule	200 mg Capsule	
Celecoxib	100	200	Active Ingredient
Lactose, NF			Diluent
Na Laury Sulfate, NF			Surfactant
Povidone, _____			Binder
Croscarmellose Na, NF			Disintegrant
Mg Stearate, NF			Lubricant
Purified H ₂ O, USP	-	-	Granulating Agent



CAS N^o: 169590-42-5

INDICATION: For relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis in adults.

DOSAGE FORM: Capsules, 100 and 200 mg

RELATED DRUG/INDs/NDAs/DMFs: _____

This is a SE-8 type of supplement submission with clinical data to support labeling claim. No new pharmacology/toxicology studies were submitted. The reviewer has performed the review on the proposed labeling (sections of "Carcinogenesis, mutagenesis, impairment of fertility" and "Pregnancy") and no new information is added.

W.C. Josie Yang, Ph.D.

Concur by team leader: Yes No

Robert Osterberg, Ph.D.

cc:

NDA 20-998
HFD-550/Division File
/JYang
/ROsterberg
/JWitters
/YKong

F/T by JYang, April 12, 2001

**APPEARS THIS WAY
ON ORIGINAL**

/s/

Josie Yang
4/12/01 11:51:41 AM
PHARMACOLOGIST

Sorry for the inconvenience! Hopefully, this will be the last time you
have to sign off.

Robert Osterberg
4/12/01 01:14:34 PM
PHARMACOLOGIST

**APPEARS THIS WAY
ON ORIGINAL**