

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-998 /S-013

MEDICAL REVIEW

Clinical Review of NDA 20-998/SCS-013
Labeling Review-Chemistry Supplement

Submission Date: 12/12/2001
Receipt Date: 12/13/2001
Review Date: 8/27/2002

Applicant: Pharmacia
4901 Searle Parkway
P.O. Box 19534
Skokie, Il 60077

Applicant's Representative: Frederick Piszkiwicz
Senior Manager, CMC
(847) 982-8961

Drug: Celebrex (celecoxib)

Pharmacologic Category: COX-2/NSAID

Submitted: This is a chemistry supplement which provides for the addition of a 400 mg strength capsule to the currently approved strengths and the addition of certain container/closure systems.

Reviewer's Comments: *The labeling has been reviewed and is acceptable. In the Dosage and Administration section for FAP, the parenthetical expression _____ that follows 400 mg should be deleted at the next printing.*

Recommendations:
The proposed labeling is recommended for approval. The applicant should revise the Dosage and Administration section as described above in the next printing.

James Witter, MD, PhD
Medical Team Leader

APPEARS THIS WAY
ON ORIGINAL

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

/s/

James Witter
8/28/02 03:14:18 PM
MEDICAL OFFICER

This is the 400 mg strength capsule supplement for Celebrex

Lawrence Goldkind
8/28/02 06:44:50 PM
MEDICAL OFFICER

APPEARS THIS WAY
ON ORIGINAL