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APPLICATION NUMBER:

20-998 / S-016

CLINICAL PHARMACOLOGY/ BIOPHARMACEUTICS REVIEW(S)

OFFICE OF CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW

NDA: 20-998 (SLR-016)	Submission Date(s): 10/8/2003
Brand Name	Celebrex® Capsules
Generic Name	Celecoxib
Reviewer	Lei Zhang, Ph.D.
Team Leader	E. Dennis Bashaw, Pharm.D.
OCPB Division	DPE III (HFD-880)
ORM division	DAAODP (HFD-550)
Sponsor	Pfizer Inc.
Submission Type	Labeling Supplement (CBE 30)

I. EXCECUTIVE SUMMARY

This labeling supplement provides for revised labeling in the Pregnancy, Nursing Mothers section of the product package insert. The sponsor submitted the literature information on the first case report documenting the excretion of celecoxib in the human breast milk in one nursing mother who received four doses of oral celecoxib 100 mg. At 4.75 hr after the fourth dose, concentrations of celecoxib in patient's breast milk were 133 and 101 ng/ml from the left and right breasts, respectively. The elimination half-life was 4.0-6.5 hours. The sponsor would like to add the statement of "Limited data indicate that celecoxib is also excreted in human milk" to replace the old sentence of "It is not known whether this drug is excreted in human milk" in the labeling.

II. LABELING COMMENTS

We agree with the sponsor in concept that the new case report suggests that celecoxib is excreted in human milk. However, we would like the label to be more reflective of the evidence we have by the following modification to the sentence: "Limited data <u>from one subject</u> indicate that celecoxib is also excreted in human milk" (underline for added text).

Lei Zhang, Ph.D.
PK Reviewer
Division of Pharmaceutical Evaluation III
Office of Clinical Pharmacology and Biopharmaceutics

Concurrence: _____

E. Dennis Bashaw, Pharm.D.
Team Leader
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Office of Clinical Pharmacology and Biopharmaceutics

CC:
NDA 20-998 (SLR-016)
HFD-550/Div File
HFD-550 (Witter/Dean)
HFD-880 (Lazor/Bashaw/L. Zhang)

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/s/

Lei Zhang
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BIOPHARMACEUTICS

Dennis Bashaw
11/5/03 04:47:04 PM
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