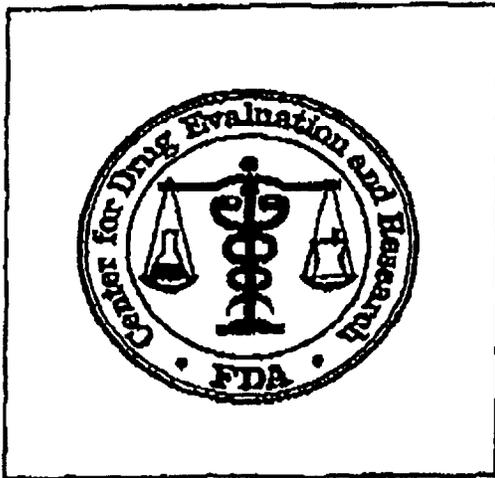




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From: Sandra Cook

*JEH*

Division of Anti-Inflammatory, Analgesic,  
and Ophthalmic Drug Products, HFD-550

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Date: *8/6/98*

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Number of Pages (INCLUDING COVER PAGE): 2

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Joy,

*ELK-8/1/98*

The following questions are from the PK reviewer for NDA 20-905:

In the patient database, used in the population pk analysis, correlation was found between smoking and drug clearance.

In the clinical trials database, was the smoker status recorded?

If so, were patients who smoked and were started off with a 10 mg dose more likely than non-smokers to be escalated to the 20 mg due to lack of efficacy?

If no studies were done using 10 mg as an entry dose, of those patients at 20 mg, was there a difference in the percentage of patients who completed the study at 20 mg (rather than having their dose reduced to 10 mg)?

Regarding your question of administering 5 20 mg tablets vs. 1 100 mg tablet as the loading

dose, the biopharmaceutical management would require demonstration of bioequivalency prior to allowing the change.

The following comment pertains the name Arava;  
The Division will accept, at this time, the use of the tradename Arava.

Please call me if you have any questions. Thanks, Sandy.