

Memo

To: Clinical Pharmacology Subcommittee Members
From: Lawrence J. Lesko, Ph.D.
CC: Rosemary Roberts, M.D., Arzu Selen, Ph.D., Richard Weinshilboum, M.D.
Date: 10/15/02
Re: Purpose of Clinical Pharmacology Subcommittee Meeting on 23 October 2002

We are looking forward to your participation in the inaugural meeting of the Clinical Pharmacology Subcommittee (CPSC) of the Advisory Committee on Pharmaceutical Sciences. Your insights, advice and recommendations will be extremely valuable to the continued development of the drug development process and science-based regulatory research and policies.

We have included background materials with this memorandum and we ask that you review them before our meeting in order for us to use our time efficiently. As you can see from the meeting agenda, we plan to cover three topics:

1. Methods to use exposure-response information in New Drug Applications to adjust doses in subpopulations where exposure is increased or decreased as a result of intrinsic or extrinsic factors. Our goal is to standardize one or more methods that we could apply routinely in regulatory review.
2. Goals and objectives for the analysis of the FDA pediatric clinical and clinical pharmacology database. We would like to get advice on what research questions and priorities would best serve pediatric public health and impact future pediatric studies, and how to go about this analysis.
3. Pharmacogenomics and the integration of diagnostic tests into drug dosing recommendations. We would like to discuss whatever issues need to be considered in the implementation of pharmacogenomic testing (genotyping or phenotyping) into product labels using TPMT as a model enzyme with a range of genetically determined activity for metabolizing thiopurines.