Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Training and Communication, Division of Training and Development
and the Committee for Advanced Science Education

CDER STAFF COLLEGE COURSE ASE 0202

Drugs and the Liver: What They Do To Each Other

April 19-20, 1999
University of Maryland, Shady Grove Campus Auditorium, Gaithersburg

Monday, 19 April 1999

8:00	Check-in, coffee	
8:30	Welcome, Course Overview	John Senior, HFD-180
8:35	The Problem of Drug-Induced Hepatotoxicity	Mac Lumpkin, HFD-002
8:45	Specific Examples (8-10 minutes each)	
	bromfenac (DURACT)	John Hyde, HFD-550
	tolcapone (TASMAR)	Judy Racoosin, HFD-120
	troglitazone (REZULIN)	Sol Sobel, HFD-510
	tasosartan (VERDIA)	Bob Fenichel, HFD-110
	zileuton (ZYFLO)	Ray Anthracite, HFD-570
	tacrine (COGNEX)	Randy Levin, HFD-120
9:45	FDA Perspective on Drug-Hepatotoxicity	Bob Temple, HFD-004
10:15	Break	
10:45	Drug metabolism and hepatotoxicity in animals; choice of animal species for testing liver effects	Sharon Center, Cornell University School of Veterinary Medicine
11:45	Pharmacology/toxicology preclinical assessments	Andrea Weir, HFD-550
12:15	Lunch	
1:15	Liver function and injury: what the tests mean	John Senior, HFD-180
1:45	What we can learn from hepatic studies in vitro	Jerry Collins, HFD-902
2:15	Human hepatotoxicity of drugs; toxicity or idiosyncracy, cellular or cholestatic?	Jim Lewis, Georgetown University Hy Zimmerman, Armed Forces Institute of Pathology, Walter Reed AMC
3:15	Break	
3:45	Detection of hepatoxicity during NDA review	Tom Laughren, HFD-120
4:15	Clinical panel discussion	Lumpkin, Temple, Senior, Lewis, Zimmerman, Lee, Laughren
5:00	Adjourn	

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8:00	Coffee	
8:30	Fialuridine and chronic hepatitis B	David Feigal, HFM-1
8:45	Evaluating drug toxicity in patients with preexisting liver disease	Will Lee, Universityof Texas, Southwestern (Dallas)
9:45	Panel--special problems in treating hepatitis	Zimmerman, Lee, Lewis, Feigal, Senior Graham, Lumpkin, Temple
10:30	Break	
11:00	Post-marketing detection of hepatoxicity	David Graham, HFD-733
11:30	Lessons learned and solutions to be found	Mac Lumpkin, HFD-730
12:00	Lunch	
1:00	Workshop description, questions for breakout groups ...with respect to drug-induced hepatotoxicity, what can be done better to: - detect it in animals and predict it in people? - use *in vitro* systems to predict it? - design clinical studies to detect it? - detect it during NDA review? - detect and characterize it post-approval?	Robert Temple; moderator
1:15	Breakout sessions to discuss questions	All Participants
2:45	Reports of breakout groups	Breakout Group Spokespersons
3:30	General discussion in plenary session Consensus & Suggestions: What Might be Done Better	Faculty and Audience
4:00	Adjourn	

Thanks for coming!