CENTER FOR DRUG EVALUATION AND RESEARCH

ADVISORY COMMITTEE: DRUG ABUSE ADVISORY COMMITTEE

DATE OF MEETING: 04/28/98

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AGENDA

Food and Drug Administration
Center for Drug Evaluation and Research

Drug Abuse Advisory Committee

Holiday Inn
2 Montgomery Village Avenue
Gaithersburg, Maryland

Agenda

April 28, 1998

The Scientific Evidence for Initiating a Scheduling Action for
***ULTRAM®** (tramadol hydrochloride),*
R.W. Johnson Pharmaceutical Research Institute,
under the Controlled Substances Act

8:30	Call to Order and Opening Remarks	Eric C. Strain, MD Chair, DAAC
	Introduction of Committee Conflict of Interest Statement	Karen M. Templeton-Somers, PhD Executive Secretary, DAAC
8:45	Introductory Remarks	Cynthia G. McCormick, MD Director, Division of Anesthetic, Critical Care and Addiction Drug Products
9:00	**Sponsor Presentation**	
	Introduction	Graham Burton, MD Vice President, Regulatory Affairs The R.W. Johnson Pharmaceutical Research Institute
	Pharmacology of Tramadol	Thomas Burks, PhD Chair, Tramadol Expert Panel Professor of Integrative Biology, Pharmacology and Physiology UT-Houston Medical School Executive Vice President for Research and Academic Affairs The University of Texas-Houston Health Science Center

Sponsor Presentation, continued

	Studies of Human Abuse Potential of Tramadol	Donald R. Jasinski, MD Professor of Medicine Johns Hopkins University School of Medicine Chief, Center for Chemical Dependency Johns Hopkins Bayview Medical Center
	Assessment of Tramadol Abuse from April 5, 1995, Until December 31, 1997: Progress Report of the Independent Steering Committee	Theodore Cicero, PhD Chairman, Independent Steering Committee Vice Chancellor for Research Washington University in St. Louis
	Clinical Issues Relating to Drug Abuse, Pain Treatment and Scheduling	Seddon R. Savage, MD Medical Consultant Pain Medicine, Addiction Medicine, Physician Health Issues Newbury, New Hampshire and Medical Director Seminole Point Hospital Chemical Dependency Treatment Center Sunapee, New Hampshire
	Epidemiology of Tramadol Abuse	Judith K. Jones, MD, PhD President, The Degge Group, Ltd.
	Summary of Major Points: Risks and Benefits Associated with the Scheduling of Tramadol and the Clinical Management of Pain	Graham Burton, MD *for* Russell K. Portenoy, MD Chairman, Department of Pain Medicine and Palliative Care Beth Israel Medical Center
	Concluding Remarks	Graham Burton, MD
11:00	Break	
11:15	Open Public Hearing I	
	Warren A. Katz, MD Philadelphia, PA	
12:00	Lunch	
1:00	Open Public Hearing II	

1:15	**FDA Presentation**	
	Regulatory History	John Hyde, PhD, MD Acting Deputy Director, Division of Analgesic & Ophthalmic Drug Products
	Introduction to the Issues	Michael Klein, PhD Team Leader, Controlled Substances Team Division of Anesthetic, Critical Care and Addiction Drug Products
	Pharmacology	David Brase, PhD Pharmacologist Division of Anesthetic, Critical Care and Addiction Drug Products
	Review of Abuse Liability Study	Igor Cerny, Pharm.D. Thomas Permutt, PhD Division of Anesthetic, Critical Care and Addiction Drug Products
	Review of Phase IV Study of Impaired Health Care Professionals	Celia Winchell, MD Medical Team Leader, Addiction Drug Products Division of Anesthetic, Critical Care and Addiction Drug Products
2:45	BREAK	
3:00	**SAMHSA Presentation** Drug Abuse Warning Network: Hospital Emergency Department Data	Janet Greenblatt, M.P.H. Statistician Office of Applied Studies, SAMHSA
3:30	**FDA Presentation**, continued Review of FDA's MedWatch Reports	Ray Alderfer, MD Division of Epidemiology and Surveillance
4:00	Committee Discussion	
5:00	Adjournment	

DRUG ABUSE ADVISORY COMMITTEE
CENTER FOR DRUG EVALUATION AND RESEARCH

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Drug Abuse Advisory Committee

Consultants to the Committee
(voting)

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Guests of the Committee
(non-voting)

Lawrence Brown, M.D., M.P.H.
Addiction Research and Treatment Corporation
22 Chapel Street
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Blanche Frank, Ph.D.
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New York State Division of Substance Abuse Services
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QUESTIONS

Questions to the Committee

1. Consider the new information about tramadol obtained since the last DAAC meeting and since marketing. What are your opinions with regard to the potential for abuse of this product?

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2. Are the reports of clinical abuse (actual) and pharmacological features of Ultram® similar to other opioids which are scheduled in the CSA? If so, which ones?

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3. The Agency would like to obtain the Committee's comments on the Independent Steering Committee as a successful deterrent to the abuse of the drug or as a useful postmarketing tool to evaluate evolving patterns of abuse. Please also explore possibilities for the future mission, goals, and duration of the ISC.

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