

Professional Flexible Labeling

An Interactive Workshop on First Principles

Review of the first interactive workshop on professional flexible labeling

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This review is intended to record and summarize the discussions and opinions expressed during the April 1995 workshop on professional flexible labeling. The synopsis of audience discussions and break-out group presentations were developed from written transcripts of this meeting (CASET Associates Ltd, Fairfax, Va). Write-ups of the individual presentations were developed by the presenters. Prior to its submission for publication, this paper was submitted for comment to Drs. Stephen F. Sundlof (FDA), Daniel A. Gingerich (AAVPT), Martin Terry (AHI), and Joe Gloyd (AVMA). Because of the critical nature of this review, it was essential that the respective representatives concurred on the accuracy of its contents.

Questions for the break-out session were developed by a committee of individuals consisting of representatives from industry, academia, government, and practitioners. Participating on this committee were Drs. Daniel A. Gingerich (Stolle Research and Development), Mark G. Papich (North Carolina State University), James E. Riviere (North Carolina State University), Charles J. Farho (the Upjohn Company), Rainer Muser (Hoechst-Roussel), Larry Rollins (FDA), Joseph Bertone (FDA), Marilyn A. Martinez (FDA), Martin Terry (AHI), and Joe Gloyd (AVMA). Questions posed by the moderators of the audience discussions (Drs. Martinez and Farho) included questions submitted by the audience participants.

The purpose of this workshop was to provide an open forum for discussing the issues that influence the kinds of information needed in professional veterinary drug labels. This objective was met through formal presentations and open discussions. Within the scope of this workshop, we considered the balance between scientific/medical concerns, regulatory requirements, and economic considerations. We discussed how labeling is currently being applied in the veterinary medical community, and explored perspectives for label improvements.

Through this forum of open discussions, we all gained insight into the drug information needs of practicing veterinarians and ways in which such information could be effectively conveyed to the veterinary medical community.

Abbreviations

CVM: Center for Veterinary Medicine	AAVPT: American Academy of Veterinary Pharmacology and Therapeutics
MIC: minimum inhibitory concentration	NCCLS: National Committee for Clinical Laboratory Standards
FARAD: Food Animal Residue Avoidance Databank	OTC: over the counter (nonprescription drug product)
FDA: Food and Drug Administration	FOI: Freedom of Information
NADA: new animal drug application	
AHI: Animal Health Institute	
AVMA: American Veterinary Medical Association	

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