NEW YORK PHARMA FORUM PROGRAM
TUESDAY, MAY 23, 2000

SPEAKERS: **Christopher-Paul Milne, D.V.M., M.P.H., J.D.,** Sr. Research Fellow, Tufts Center for the Study of Drug Development, Tufts University
Janeth Turner, Director, Worldwide Regulatory Affairs, Parke Davis Pharmaceutical Research, Warner Lambert Company

TOPIC: ***Complying with New FDA Regulations for Clinical Drug Testing in Children***

One of the many provisions of the recent Food and Drug Administration Modernization Act (FDAMA) provides for an additional period of market exclusivity in exchange for completed pediatric studies requested by the FDA for certain drugs of potential benefit to children. The origin of this law centers around two facts: drugs needed by children lack labeling for pediatric use, and industry lacks the incentive to perform studies to support this additional labeling. Since Congress has now provided the incentive, the success of the new law will rest initially on industry's willingness and readiness to do the studies, according to Dr. Christopher Milne.

Dr. Milne, who is a frequent writer and speaker about pediatric research will give an overview and update on this timely issue. Ms. Turner will provide a case study based on her experience as a pharmaceutical manufacturer with FDA approvals.

Dr. Milne's current research efforts are directed at examining legislative initiatives for special patient populations, assessing the growth and utilization of the outsourcing industry, and evaluating the impact of provisions of the FDA Modernization Act.

Ms. Turner, with 33 years pharmaceutical research experience, is responsible for working with FDA on the approval of New Drug Applications. Most recently, she had regulatory responsibility to obtain FDA's granting of additional market exclusivity based on pediatric studies of Neurontin, a drug currently approved for the treatment of epilepsy in adults.