FDA Regulatory and Enforcement Update
November 12, 2003
9:00 a.m. - 12:00 a.m.

Moderator: Peter Barton Hutt, Partner, Covington & Burling

Session I: 9:00-10:30: Unapproved Uses of Approved New Drugs

The DOJ Position
Thomas E. Kanwit
Assistant U.S. Attorney
Health Care Fraud Unit
District of Massachusetts

The FDA and Industry Positions
Peter O. Safir
Partner, Covington & Burling

Session II: 10:30 - 12:00: FDA Drug GMP Requirements

The FDA GMP Initiative
Joseph Famulare
Director, Division of Manufacturing and Product Quality
Office of Compliance
FDA Center for Drug Evaluation and Research

The Industry Concerns About GMP Requirements
Richard F. Kingham
Partner, Covington & Burling