

Industry Update

August 3, 2004

The Minor Use Minor Species Animal Health Act of 2004 (MUMS) was signed into law by President Bush on August 2, 2004.

While the MUMS legislation creates several new incentives, most prominent are the conditional drug approval and the index of legally marketed unapproved drugs (drug index). Each has certain advantages and limitations. Additional incentives include safeguards that have been created to protect existing New Animal Drug Approvals (NADA) from unwarranted scrutiny should a pharmaceutical company attempt to supplement the existing approval to address minor animal species or minor uses. The legislation also creates a new approach to facilitating drug development through a designated new animal drug classification system. Designated new animal drugs are eligible for grants for safety and efficacy testing, and for manufacturing process development. Designated drugs are also eligible for an exclusive seven year marketing time period. A new Office of Minor Use and Minor Animal Species Drug Development is created whose mission is to issue the grants, determine eligibility for listing on the drug index and for serving as a liaison amongst government agencies to improve opportunity for drug approvals.