OCTOBER 24, 2008

ADVISORY RE CLINICAL DRUG TRIAL REPORTING

To manufacturers and labelers of prescription drugs:

By letter dated September 15, 2008, from Trish Riley, Director of the Governor's Office of Health Policy and Finance, Maine notified drug manufacturers that it will look to future postings of results on www.ClinicalTrials.gov starting December 8, 2008, for compliance with the Maine statute and rules governing clinical drug trial results reporting. We have been asked to clarify our position with respect to the reporting of adverse events. The September 15, 2008, letter specified the data elements that must be completed, including those for adverse events reporting. Maine no longer will require textual summaries (i.e., ICH E3 format) of results reporting that are not accommodated by the available fields on www.clinicaltrials.gov.

Maine is applying its state laws in requiring the completion of these data fields. The ClinicalTrials.gov website meets the definition set forth by the Maine rule for a publicly funded website, and completion of the adverse events data elements is consistent with section 1.03-2(A) of the rule Section 1.03-2(A) expressly requires the reporting of results information on the safety of the drug under trial.

The adverse events data elements conform to the default adverse events information specified by federal law (see 42 U.S.C. 282(j)(3)(I)(ii)). Maine notes that the absence of any proposed federal rule on this topic as of yet indicates that a federal rule is unlikely to be adopted by March 27, 2009. Maine anticipates that the adverse events data elements will not change substantially when the federal statutory requirements take effect on September 27, 2009.