STATE OF MAINE
GOVERNOR'S OFFICE OF HEALTH POLICY AND FINANCE
15 STATE HOUSE STATION
AUGUSTA, MAINE 04333-0078

JOHN E. BALDACCI
GOVERNOR

TRISH RILEY
DIRECTOR

September 15, 2008

Dear Sir or Madam:

Current Maine statute and rule require manufacturers of prescription drugs to publish results of hypothesis-testing clinical trials of FDA-approved drugs if the drug is available in Maine and if the trial was initiated after October 15, 2002. This letter is to direct your company to a National Institutes for Health website for the future reporting of results information.

Please note that the Maine statute and rule requiring clinical drug trial registration and results reporting remain in force and are not yet preempted by federal statute. Until federal rules are adopted that fully implement federal requirements for results reporting, Maine's requirements remain legally enforceable.

The Maine rule, which became effective in March of 2007, requires that the results be published "on a publicly funded Internet website or, if not available for such posting, a publicly accessible Internet website." The rule defines a publicly funded internet website as www.clinicaltrials.gov.

Up until now, no publicly funded internet website has been available for results reporting.

Starting September 27, 2008, however, www.clinicaltrials.gov will be available for the posting of results information. **Beginning September 27, 2008, completion of all relevant reporting elements in the "basic results" data entry system at www.clinicaltrials.gov, will be regarded by Maine as satisfying all elements of results reporting specified in the Maine rule, regardless of any discrepancy between the fields of that website and the Maine rule.** This includes completion of all required data elements and any relevant optional elements in each of the following ClinicalTrials.gov "basic results" reporting categories: Results Point of Contact, Certain Agreements, Participant Flow, Outcome Measures, and Adverse Events. Maine encourages your company to begin using this website when it first becomes available for results reporting. However, its use will become mandatory under existing Maine requirements.

After December 8, 2008, Maine will not recognize the reporting of trial results on any other website as satisfying the reporting requirements of the Maine rule.

More, up-to-date information about www.clinicaltrials.gov is available by going to http://prsinfo.clinicaltrials.gov/fdaaa.html. Please note that results reporting on a clinical trial is

dependent upon that trial having been registered on the site. The trial registration requirements set by the Maine rules have not changed.

Regarding trial results that already have been posted to a publicly accessible internet website in compliance with the Maine rule, the Maine rule does not require a manufacturer to re-post those results onto www.clinicaltrials.gov. However, Maine encourages manufacturers to re-post such results and anticipates considering the adoption of such a requirement in future rule-making.

Several issues have arisen in the context of the Maine rule that would benefit from clarification.

One issue is whether a reanalysis of data from a clinical drug trial requires a new reporting of results. Under the present rule, Maine takes the position that a reanalysis of data, if it represents a meaningful or a substantial revision of previously reported results, does require a new reporting of results. In addition, a reanalysis of data that is used for marketing, promotional or educational purposes also constitutes results that must be reported.

The Maine rule requires the reporting of results of bioequivalency trials. As enacted, the federal law (FDAAA) enacted last year also appears to require the reporting of results of bioequivalency trials, as bioequivalency trials presumably do not qualify as exempted Phase I trials. While Maine has not yet taken any enforcement action regarding the reporting of bioequivalency trial results, they must be reported as a matter of Maine rule and ultimately under federal law.

For reference, the Maine statute applicable here is 22 M.R.S.A. §2700-A, and the Maine rule is Department of Health and Human Services 10-144, chapter 225, Section 1, jointly adopted as Office of Attorney General 26-239, chapter 111, Section 1.

Thank you for your attention to this matter.

Sincerely,

Trish Riley
Director
Governor's Office of Health Policy and Finance