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GOVERNOR

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

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October 12, 2005

Dear Prescription Drug Manufacturer,

This letter is meant to provide you with additional information on the implementation of Maine's new law, "An Act Regarding Advertising by Drug Manufacturers and Disclosure of Clinical Trials," a law which affects your business.<sup>1</sup> We have appreciated guidance from the industry about how best to streamline this process.

Beginning October 15, 2005, a manufacturer or labeler of prescription drugs dispensed in Maine that employs, directs or utilizes marketing representatives in Maine shall disclose its clinical trials and information concerning the results of clinical trials on a publicly accessible website. The Maine law applies to trials of prescription drugs conducted or sponsored by the manufacturer on or after October 15, 2002.

To implement this section of the Statute, the Maine Office of Public Health will host a Clinical Trials Website. The website can be accessed at the following address  
[http://www.maine.gov/dhhs/boh/clinical\\_trials.htm](http://www.maine.gov/dhhs/boh/clinical_trials.htm) effective October 15, 2005.

The following are an initial list of links that will be housed on this website:

- <http://www.clinicaltrials.gov>
- <http://www.clinicalstudyresults.org>
- <http://www.lillytrials.com>
- <http://www.centerwatch.com/patient/results/default.asp>
- <http://www.roche-trials.com/results.html>
- <http://www.forestclinicaltrials.com/CTR/CTRController/CTRHome>
- <http://www.bayerhealthcare.com>
- <http://www.astrazenecaclinicaltrials.com>
- <http://www.novartisclinicaltrials.com/clinicaltrialrepository/public/login.jsp>

If a company lists its publicly disclosed human-subject trials on any of these publicly accessible websites and posts on any of these publicly accessible websites all its clinical trial results that have been publicly disclosed, the Governor's Office of Health Policy and Finance will consider the manufacturer to be compliant with this initial phase of implementation until rules to more

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<sup>1</sup> See 22 M.R.S.A. c. 605, §2700-A.

fully implement the statute are adopted or until further notice by this Office. In this instance, the term, “publicly disclosed,” does not include required disclosures of information to the FDA that retains confidentiality. As specified in the Maine law, the information posted in reference to each listed clinical drug trial must include the name of the entity that conducted or is conducting the clinical trial, a summary of the purpose of the clinical trial and the dates during which the trial has taken place.

The Department of Health and Human Services, in cooperation with the Governor’s Office of Health Policy and Finance, is currently drafting rules. We will share drafts rules with you when they become available and appreciate the opportunity to address your concerns.

You may contact Jude Walsh, Pharmacy Affairs Coordinator, with questions at 207-624-9844 or [jude.e.walsh@maine.gov](mailto:jude.e.walsh@maine.gov). However, for most questions, you are urged to seek the advice of legal counsel. Thank you.

Sincerely,

Trish Riley, Director  
Governor’s Office of Health Policy and Finance