

## Memo

To: Manufacturers of Prescribed Products

From: Wendy Morgan, Chief of Public Protection Division  
Vermont Office of the Attorney General

Date: September 24, 2010

Subject: Notice re FY10 Reporting of Clinical Trials and  
Conference Call on Draft 2011 Guide on Samples Reporting

### **Clinical Trials**

For any bona fide clinical trial, the manufacturer shall report either the expenditures associated with the trial, or the minimum information regarding the clinical trial, to the Attorney General at the close of the fiscal year in which the trial began. Thus, you have an obligation to report by October 1, 2010, on clinical trials for which there were expenditures between July 1, 2009, and June 30, 2010.

I understand that some companies are discussing Vermont's different definitions of clinical trials, bona fide clinical trials, and research projects. The "Purpose of Expenditure" for all expenditures of this nature should be reported within the FY10 categories of "Bona Fide Clinical Trial" or "Research Project." No one will be penalized for putting expenditures in the wrong category; they could be penalized for failing to report all such expenditures. We can discuss at a later time whether the definitions might be amended for ease in categorization.

If the clinical trial started after July 1, 2008, and the FDA has not yet approved or cleared the prescribed product, you need only send the Delayed Disclosure/Minimum Information regarding clinical trials. To send Minimum Information, please use the following method (outlined in the FY11 Guide):

Send the minimum clinical trial information to the Attorney General in an email to: [prescribedproducts@atg.state.vt.us](mailto:prescribedproducts@atg.state.vt.us), with "clinical trial notification" in the subject line. The minimum information is: the name of the clinical trial, the start date, and the web link to the clinical trial registration on the national clinical trials registry.

You may send that information in the body of the email or, if you have many trials to report, in an excel spreadsheet attached to the email.

## **2011 Guide to Disclosure of Samples**

I had planned to distribute a draft of the guide to you in advance of a conference call next week, but I now understand that many of the same people who would want to be on the conference call are responsible for submitting disclosures by October 1. I also understand that some of you may want to discuss the draft before the conference call, to organize your thoughts, and – I hope – to come up with specific proposals for improvement.

Consequently, I will send you the draft 2011 Samples Guide next week. The conference call will be:

Tuesday, October 12 at 1pm Eastern Time

Toll free: 1-888-757-2790

Pass code: 134936#