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(a joint rule with)

26-239, Chapter 111: OFFICE OF ATTORNEY GENERAL  
REPORTING AND FEE REQUIREMENTS FOR PHARMACEUTICAL MANUFACTURERS AND  
LABELERS

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SECTION 1      PRESCRIPTION DRUG CLINICAL TRIAL REPORTING    ESTABLISHED 3/1/07  
LAST UPDATED: 11/02/09

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**1.03    DISCLOSURE OF TRIALS OF DRUGS AND BIOLOGICAL PRODUCTS (Cont.)**

Eff.  
11/2/09

reasons for the delay and the actions previously taken and to be taken in the future by the manufacturer or labeler to ensure posting on such publicly funded website. A manufacturer or labeler in compliance with this paragraph is exempted from the applicable time requirement insofar as it demonstrates that the cause of the delay is and remains solely the agency's or its website.

Eff.  
11/2/09

1.03-6 **Exemptions from revisions.** Investigations or studies registered prior to January 1, 2010, are exempt from newly imposed revisions within section 1.03-1 of this rule. Results of investigations or studies submitted for posting prior to January 1, 2010, are exempt from newly imposed revisions within section 1.03-2, except that the requirement to report post hoc analysis applies if the analysis was completed after January 1, 2010, regardless of the date of the previously reported results. Any posting requirement preceding the adoption of revisions of this rule does not qualify as a newly imposed requirement. Observational (non-interventional) investigations or studies completed prior to January 1, 2010, are exempt from any newly created application of this rule.

**1.04    SUBMISSION SCHEDULE**

1.04-1 **Clinical Trial Registries**

- A.    **Completed or discontinued covered clinical trials.** In the case of any completed or discontinued covered clinical trial, the manufacturer or labeler shall post the information described in section 1.03-1 by the latest of the applicable dates below:
- (1)    the first date the drug or biological product is either dispensed, administered, delivered or promoted in this State for any indication; or
  - (2)    twenty-one (21) days after patient enrollment has begun.
- B.    The manufacturer or labeler shall have 120 days after the adoption of revisions to these rules to post the information described in section 1.03-1 on trials not previously required to be reported by these rules.

1.04-2 **Clinical Trial Results Databases.**

- A.    In the case of any completed or discontinued covered clinical trial, the manufacturer or labeler shall post the information described in section 1.03-2 in accordance with the following schedule:
- (1)    one (1) year (plus provided extensions) after the date on which the trial was completed; or





