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IF YOU'VE EVER BEEN ISSUED AN FDA 483, you know the importance of responding to these observations by describing your corrective actions to avoid further Agency action which could include the issuance of a **Warning Letter**.

*You know that you generally have 15 days in which to respond. Did you know that responses received **after** 15 days may be ignored by the Agency?*



ACCORDING TO THE FEDERAL REGISTER, VOL. 74, NO. 153 DATED AUGUST 11, 2009.

“...the agency will not ordinarily delay the issuance of a warning letter in order to review a response to an FDA 483 that is received more than 15 business days after the FDA 483 was received.”

Now, more than ever, you must be kept informed about issuance of 483 observations and how they can be used to train your staff, keep your facility in compliance and prepare you for your next inspection. View recent 483 observations by subscribing to *GMP TRENDS*.



STAY IN COMPLIANCE!

Subscribe to GMP TRENDS and help eliminate the issuance of 483's that could result in a **Warning Letter**.



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