Minivelle Vivelle Shortages Explained

Minivelle and Vivelle continue to be in short supply in most pharmacies across the country. Initially, I was not able to determine any reason. Nothing revealed by simple Google searches. No FDA drug recalls. Not evident from FDA drug shortage surveillance lists.

Now, one of my astute and persistent patients was able to track down the reason. The FDA has been very critical of testing and quality assurance methods for this product. Adherence to CGMP. Current Good Manufacturing Practices. The reasons seem sound but are not technically safety related.

Here is the full FDA warning letter which is long and tedious. It is illuminating for you.

The summary is quite ominous — dated Aug 05 2016:

> *Violations cited in this letter are not intended to be an all-inclusive list. You are responsible for investigating, for determining the causes, for preventing their recurrence, and for preventing other violations.*

> *If you are considering an action that is likely to lead to a disruption in the supply of drugs produced at your facility, FDA requests that you contact CDER's Drug Shortages Staff immediately, at drugshortages@fda.hhs.gov, so that FDA can work with you on the most effective way to bring your operations into compliance with the law. Contacting the Drug Shortages Staff also allows you to meet any obligations you may have to report discontinuances or interruptions in your drug manufacture under 21 U.S.C. 356C(b) and allows FDA to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products.*

> *After you receive this letter, you have 15 working days to respond to this office in writing. Specify what you have done since our inspection to correct your*

violations and to prevent their recurrence.

Based upon the nature of the violations we identified at your firm, we strongly recommend engaging a consultant qualified as set forth in 21 CFR 211.34, to assist your firm in meeting CGMP requirements. Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm's executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance.

If you cannot complete corrective actions within 15 working days, state your completion date and reasons for delay.

Bureaucratic Over-reach

Quite frankly, this is how we force good companies out of business. Oppressive bureaucratic dictates.

The same with recent lipid testing with the plaque LpPla2 test for oxidized LDL. Forced out of business. Because of impossible compliance requirements. This is not necessarily in your best interest. Bureaucratic over reach is legendary. And sometimes, as in this case, there is an inference of personality conflicts.

The generic houses such as Mylan that are producing the knock off product may not be as effective. They are never subject to the same level of scrutiny as the original manufacturer. And you are being forced, by state law, to accept generic knockoffs unless you specifically protest. "No generics." Since this is a cost issue, most of you will not contest the automatic substitution of generics for the brand name.

There is no doubt that the cost of the brand names is out of sight which only complicates this issue further. You accept inferior products in the name of saving costs. What is your health and happiness worth to you? The never ending question. What is your well being worth? Estrogen is your friend and life saver.

Call This Number

You can call this number, 1-800-320-3789, for a list of pharmacies in your area that might still have Minivelle or Vivelle in stock. The list is growing shorter by the week. Tell me if you find new information that I can share with my audience.