Hello Dana,

I just left you a voice mail regarding the mycoplasma testing used for the Quadracel lots. We are aware that a new method has been proposed, and possibly even used for the Quadracel lots to be released. We have a significant issue if the new, unapproved, mycoplasma testing has been used for the Quadracel lots.

If the new unapproved method was used for Quadracel, we need you to quickly submit a CBE 30 supplement to the Pentacel file for approval. Be advised, if changes are deemed anything less than minor, we may change the supplement to a PAS. If it is submitted quickly, and approved, there may be not issued with the Quadracel lots or file. However, if there is an issue with the new mycoplasma testing, and it was used for the Quadracel lots, we will most definitely have an issue. If you can revert to the approved mycoplasma testing, any issues may be avoided.

Additionally, we are still awaiting a response to our May 13, 2014 information request concerning a comprehensive list of what is being cross-referenced to the Pentacel file and if any Pentacel CRs will complicate the Quadracel file.

Please call me or respond to this e-mail as soon as possible for resolution of these issues.

Thanks,

juan

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