11/10/2023

To Monica Maxwell
Program Division Manager, FDA
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Subject: *Appeal petition from Hybrid Pharma not to publish the 483 issued on 11/9/2023 by FDA investigator Ms. King in public domain without amending or modifying.*

Last night Hybrid Pharma (Hybrid) received a 483 from FDA investigator Ms. King. Hybrid is not agreeing several inspectors' observations in the 483. Some of the evidences were overlooked, and never consulted before issuing the 483. We request the agency to amend this 483 issued on Nov. 9th, 2023 to remove non-factual information and misleading statements. A few examples are shown here.

1. The inspector noted stain(s) in the HEPA filter. The inspector failed to address the Environmental Monitoring (EM) data presented and also witnessed the EM data collected during her inspection of compounding process.

2. The 483 questions the certification of clean room with reference to the smoke studies, performed by an independent clean-room testing company following CETA guidelines. The simulation of the production process under smoke studies illustrates the efficiency of the Laminar Flow Hood and the performance is proved to be good. The investigator also witnessed that the capping was performed in ISO 7.

3. The investigator overlooked the Media fill test results. In the 483, citations of 2017 and 2019 Media Fill simulations are mentioned but not Hybrid's data and the responses as of those years and also got cleared in 2021 inspection. The results showed Hybrid was in compliance in 2017 and 2019 and continue to be so. Please refer those reports. In this 2023 inspection also, the proper related documents were not reviewed before finalizing the 483. We presented the related documents during closing but did not collect the same documents.

4. Regarding Iodometric titration assay for ascorbic estimation, there is a pending Citizen's petition with the FDA commissioner. In the meantime, Hybrid is performing HPLC assay method few months back by the request of the FDA and all the related documents were presented to the investigator during inspection. There is no reason to mention the Ascorbic acid iodometric titration in the 483 in multiple locations.

5. Reporting of the finished products in the FDA portal is challenging for Hybrid for several years. This was discussed in the FDA stakeholder meeting and Hybrid is working with the FDA to sort out this issue. The investigator was shown the computer screen at Hybrid and explained the factual and actual problems in the reporting portal.

In summary, THIS 483 dated Nov.9, 2023 write-up damages Hybrid Pharma in multiple ways by publishing wrong information in public domain. Please give some time to sort out this issue as soon as possible. In the meantime, we are working hard in replacing the stained HEPA filters as well as better documentation. The progress will be updated to you.

Kindly acknowledge this communication and expecting your reply as soon as possible.

Sincerely,

Dr. P. Rajalingam Ph.D.

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