precisionscience®
MANUFACTURING ANIMAL HEALTH

May 26, 2023

memorandum

Bill Bookout
NASC
PO Box 5168
Sun City West, AZ 85376

Dear Bill:

The purpose of the memo to clarify Precision Science's compliance status as it relates to the FDA and subsequent compliance with the NASC's regulatory and acceptance criteria/guidelines.

Produced at the facility are FDA regulated articles conforming to:

- CFR 111 (cGMP for manufacturing, packaging, labeling for dietary supplements)
- CFR 211 (cGMP for finished pharmaceuticals)
- CFR 225 (cGMP for medicated feeds)
- CFR 226 (cGMP for type A medicated articles)

In general, the CFR 111 cGMP requirements, although similar, are less stringent and tend to be more flexible than the CFR 211 cGMP requirements. However, a few areas the CFR 111 requirements are more explicit or detailed than CFR 211, such as necessary documentation for equipment or instrument calibration [111.35(b)(3)] and material review/disposition [111.140(b)(3)]. Where applicable, Precision Science in conjunction with our client partners have adopted the more stringent measures required of CFR 211. This is particularly important as we manufacturer both medicated and supplement products for animal health.

Precision Science also complies with CFR 507 (cGMP hazard analysis and risk based preventative controls for food for animals).

Please advise if you have any further questions or require further documentation on the above matter.

Regards,

Bryan K. Vincent

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