IND 110513 Microbiology Comments

Baig, Iram [redacted]
Thu 1/19/2023 8:20 AM
To: Shannon DiNapoli [redacted];Berra Yazar-Klosinski [redacted]

Dear Shannon,

Reference is made to IND 110513 and the submission dated December 6, 2022 (SN 0028), containing your response to our information request. We have the following recommendations from the Division of Microbiology Assessment (DMA):

1. Your response that the acceptance criteria listed in Table 2 *Recommended Microbial Limits for Botanical Ingredients and Products-Dried or Powdered Botanicals* of USP <2023> are being used because the *Cannabis and Cannabis-derived Compounds* guidance defines cannabis as a botanical raw material, botanical drug substance, or botanical drug product is acknowledged. However, your assumptions are not correct. Table 2 of USP <2032> *Microbiological Attributes of Nonsterile Nutritional and Dietary Supplements applies specifically to raw materials, pharmaceutical ingredients, and active ingredients used in the manufacture of nutritional and dietary articles*…. Cannabis used in clinical trials, although botanical material, is considered a drug product and not a nutritional or dietary article. The recommendations for testing and acceptance criteria for the cannabis products used in your studies should be derived from Table 1 of USP <1111> *Microbiological Examination of Non-sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use*. Therefore, work with your supplier to revise the cannabis drug product and cannabis placebo final specifications to reflect the microbiological testing acceptance criteria for Total Aerobic Microbial Count (TAMC) and Total Yeast and Mold Count (TYMC) as defined in USP <1111> *Microbiological Examination of Non-sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use* for non-sterile, non-aqueous inhaled drug products.

Please let me know if you have any questions.

Kind Regards,
Iram

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