Re: IND 110513 - Type A Mtg - attendees

Allison Coker <[redacted]>
Mon 6/19/2023 11:12 AM
To:Magda, Valerie <[redacted]>;Baig, Iram <[redacted]>
Bcc:Allison Coker <[redacted]>

Dear Valerie and Iram,

Thanks to you both and the team at FDA for a collaborative dialogue at our Type A meeting on Study MJP2 under IND 110513 last week. We appreciate you sending the attendee list for our records. We recognize that the revised research objective of Study MJP2 was not adequately or consistently highlighted in previous responses to the clinical hold. We found the hybrid meeting format with the in-person component to be very helpful in clarifying that point and in moving the discussion forward toward what we hope will be an acceptable clinical response.

During the meeting several questions arose that the Division offered to provide post-meeting comments on after obtaining input from the pulmonary team. I wanted to make good on our offer to summarize those questions here:

- MAPS is considering reintroducing vaporization as a method of administration using the PAX 2 flow vaporizer device into Study MJP2. This device is currently being used in other cannabis IND studies. Recognizing that MAPS will be required to provide device information regarding the PAX 2 device, are there any non-device-specific safety concerns related to dried cannabis flower vaporization as a method of administration in Study MJP2? If there are any concerns, we would like to be able to address them proactively in the next response.
- The Division raised a concern regarding smoking as a method of administration in light of the pulmonary effects of combustion. Because the risks of combustion are already present in experienced smokers of tobacco or cannabis and because Study MJP2 is a 5-week study, would the risk be deemed reasonable if Study MJP2 were conducted in such patients?
- The concern regarding cannabis naïve subjects appears largely related to combustion. We would like to specifically understand if the Division believes the risks of this 5-week study may be acceptable in cannabis naïve subjects with a history of smoking tobacco. We also discussed using a population of cannabis naïve subjects who have already made a decision to use cannabis and would appreciate the Division's view of the acceptability of this population.

We look forward to receiving your minutes. Finally, the IMP is currently undergoing stability testing to meet the requirements by the Division. We plan to submit a response to the clinical issues in advance of the completion of the CMC information and request that the Division review the clinical portions of the hold while the stability information is in progress. Please let me know if you have any questions.

With gratitude,
Allison

Allison Coker, PhD (she/her)
Program Manager
Multidisciplinary Association for Psychedelic Studies (MAPS)

From: Magda, Valerie <[redacted]>
Sent: Friday, June 16, 2023 8:50 AM
To: Allison Coker <[redacted]>; Baig, Iram <[redacted]>; Charleen Justice <[redacted]>
Subject: IND 110513 - Type A Mtg - attendees

Dear Allison,

Below are the list of FDA attendees as requested:

Teresa Buracchio, MD	Director (acting), Office of Neuroscience
Tiffany R. Farchione, MD	Director, Division of Psychiatry (DP)
Valentina Mantua, MD	Clinical Team Lead, DP
Ikram Elayan, PhD	Pharmacology/Toxicology Supervisor, Division of Pharmacology and Toxicology for Neuroscience (DPT-N)
Antonia Dow, PhD	Pharmacology/Toxicology Team Lead, DPT-N
Yongbin Zhang, PhD	Pharmacology/Toxicology Reviewer, DPT-N
Venkateswaran ChithambaramPillai, PhD	Clinical Pharmacology Team Leader (acting), Office of Clinical Pharmacology (OCP)
Kofi Kumi, PhD	Clinical Pharmacology Reviewer, OCP
Peiling Yang, PhD	Biometrics Team Leader, Office of Biostatistics (OB)
Kelly Yang, PhD	Biometrics Reviewer, OB
Charles Wu, PhD	Botanical Review Team Lead, Office of Pharmaceutical Quality (OPQ)
Eric Bow, PhD	Drug Product Reviewer, OPQ
Valerie Magda, PharmD	Regulatory Project Manager, Division of Regulatory Operations for Neuroscience-Psychiatry Group
Tyler Osselborn	Pharmacy Student

Best regards,
Valerie