IND 110513

**MEETING REQUEST GRANTED**

Multidisciplinary Association for Psychedelic Studies (MAPS)
Attention: Rick Doblin, PhD
Founder and President
3141 Stevens Creek Blvd. #40563
San Jose, CA 9511

Dear Dr. Doblin:[1]

Please refer to your investigational new drug application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for marijuana, Cannabis sativa.

We also refer to your April 28, 2023, correspondence requesting an in-person Guidance meeting, to gain agreement from the Agency on the sufficiency of the safety information to support the proposed dosing paradigm, proposed administration instructions, and inclusion of cannabis-naïve participants. Based on the statement of purpose, objectives, and proposed agenda, we consider the meeting a type A meeting.

In 2023, CDER and CBER staff are transitioning to a hybrid workplace, with staff returning to work at the White Oak (WO) campus (on-site) for a portion of their work time. This transition will enable face-to-face in-person formal meetings between FDA and Industry. To avoid overcrowding in the conference rooms, FDA will focus on having only core participants with a primary speaking role in-person while others join virtually. FDA encourages Industry to follow this same pattern. Therefore, all face-to-face in-person formal meetings will have a hybrid component (virtual attendees in addition to in-person attendees). To support hybrid meetings, WO conference rooms are being upgraded, in phases, over the course of 2023 with new technology (e.g., noise-cancelling, boom-forming microphones, face/conversation tracking video cameras). The availability of hybrid conference rooms will initially limit the number of in-person meeting requests that can be granted. The number of meetings that can be granted and held in-person with a hybrid component will increase as conference rooms are upgraded over the course of 2023. Updates on FDA's transition to face-to-face in-person formal meetings will be communicated in advance on the FDA.gov website[2].

Beginning February 13, 2023, due to the initially limited availability of upgraded conference rooms, CDER and CBER will begin scheduling face-to-face in-person Industry meetings (with a hybrid component) starting with Type A, BPD 1, and Type X

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.
[2] https://www.fda.gov/industry/prescription-drug-user-fee-amendments/update-person-face-face-formal-meetings-fda

meeting requests. Face-to-face meeting requests for other meeting types, if granted, will be held as virtual meetings (i.e., the in-person format will not be considered).

CDER and CBER will be monitoring conference room upgrades monthly and as upgrades are completed, we will transition in phases such that all types of face-to-face formal meetings can be considered for in-person. For example, Phase 2 of this transition would permit the consideration of Type A and Type B (milestone), BPD Type 1 and BPD Type 2, Type X and Type Y face-to-face formal meetings to be considered for in-person scheduling. The final phase of this transition will enable any face-to-face formal meeting to be considered for in-person format.

We have considered your request for a face-to-face in-person meeting. Because we have been able to identify a suitable WO conference room AND your meeting falls into one of the prioritized meeting types, we are able to grant your request as a face-to-face in-person meeting.

The meeting is scheduled as follows:

**Date:** Thursday, June 15, 2023
**Time:** 11:00AM to 12:00PM EDT
**Location:** [redacted]

**Virtual Arrangements:** ZoomGov details will be sent closer to meeting date

**Invited CDER Participants (tentative):**

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|---|---|
| Tiffany R. Farchione, MD | Director, Division of Psychiatry (DP) |
| Valentina Mantua, MD | Clinical Team Leader, DP |
| Roberta Rasetti, MD | Clinical Reviewer, DP |
| Iram Baig, MS | Regulatory Project Manager, Division of Regulatory Operations for Neuroscience-Psychiatry Group |

In accordance with 21 CFR 10.65(e) and FDA policy, you may not electronically record the discussion at this meeting. The official record of this meeting will be the FDA-generated minutes.

Logistical support for this meeting will be provided by our Sponsor Meeting Support Team. If you have secure email, you will be receiving an email from our team with information pertaining to your visit, including information for non-U.S. citizen visitors to FDA.

The email will be sent from OND-Sponsor-Meetings-Support@fda.hhs.gov and will provide guidance on security and parking information. If you do not have secure email, you will receive this information via fax. Direct any questions regarding meeting logistics to our support team using the above email address.

We acknowledge receipt of the meeting package included with the meeting request. If the materials presented in the meeting package are inadequate to prepare for the meeting, we may cancel or reschedule the meeting.

## SECURE EMAIL

Secure email is required for all email communications from FDA when confidential information (e.g., trade secrets, manufacturing, or subject information) is included in the message. To receive email communications from FDA that include confidential information (e.g., information requests, labeling revisions, courtesy copies of letters), you must establish secure email. To establish secure email with FDA, send an email request to SecureEmail@fda.hhs.gov. Please note that secure email may not be used for formal regulatory submissions to applications (except for 7-day safety reports for INDs not in eCTD format).

## ADDITIONAL IND RESPONSIBILITIES

As sponsor of this IND, you are responsible for compliance with the FDCA (21 U.S.C. §§ 301 et. seq.) as well as the implementing regulations [Title 21 of the Code of Federal Regulations (CFR)]. A searchable version of these regulations is available online for your convenience.[3] Your responsibilities include:

- Reporting any unexpected fatal or life-threatening suspected adverse reactions to this Division no later than 7 calendar days after initial receipt of the information [21 CFR 312.32(c)(2)].

- Reporting any (1) serious, unexpected suspected adverse reactions, (2) findings from other clinical, animal, or in-vitro studies that suggest significant human risk, and (3) a clinically important increase in the rate of a serious suspected adverse reaction to this Division and to all investigators no later than 15 calendar days after determining that the information qualifies for reporting [21 CFR 312.32(c)(1)]. Submit 15-day reports to FDA electronically in eCTD format via the ESG; and

[3] https://www.ecfr.gov/cgi-bin/text-idx?SID=3ee286332416f26a91d9e6d786a604ab&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl

- Submitting annual progress reports within 60 days of the anniversary of the date that the IND became active (the date clinical studies were permitted to begin) [21 CFR 312.33].

## SUBMISSION REQUIREMENTS

The Electronic Common Technical Document (eCTD) is CDER and CBER's standard format for electronic regulatory submissions. Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information, visit FDA.gov.[4]

The FDA Electronic Submissions Gateway (ESG) is the central transmission point for sending information electronically to the FDA and enables the secure submission of regulatory information for review. Submissions less than 10 GB must be submitted via the ESG. For submissions that are greater than 10 GB, refer to the FDA technical specification *Specification for Transmitting Electronic Submissions using eCTD Specifications*.[5]

## DATA STANDARDS FOR STUDIES

Under section 745A(a) of the FD&C Act, electronic submissions "shall be submitted in such electronic format as specified by [FDA]." FDA has determined that study data contained in electronic submissions (i.e., NDAs, BLAs, ANDAs and INDs) must be in a format that the Agency can process, review, and archive. Currently, the Agency can process, review, and archive electronic submissions of clinical and nonclinical study data that use the standards specified in the Data Standards Catalog.[6]

On December 17, 2014, FDA issued the guidance for industry *Providing Electronic Submissions in Electronic Format--- Standardized Study Data.* This guidance describes the submission types, the standardized study data requirements, and when standardized study data are required. Further, it describes the availability of implementation support in the form of a technical specifications document, Study Data Technical Conformance Guide,[7] as well as email access to the eData Team (cder-edata@fda.hhs.gov) for specific questions related to study data standards. Standardized study data are required in marketing application submissions for clinical and nonclinical studies that started after December 17, 2016. Standardized study data

[4] http://www.fda.gov/ectd
[5] https://www.fda.gov/drugs/forms-submission-requirements/electronic-regulatory-submission-and-review
[6] http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm
[7] https://www.fda.gov/media/88173/download

are required in commercial IND application submissions for clinical and nonclinical studies that started after December 17, 2017. CDER has produced a Study Data Standards Resources web page[8] that provides specifications for sponsors regarding implementation and submission of clinical and nonclinical study data in a standardized format. This web page will be updated regularly to reflect CDER's growing experience in order to meet the needs of its reviewers.

For commercial INDs and NDAs, Standard for Exchange of Nonclinical Data (SEND) datasets are required to be submitted along with nonclinical study reports for study types that are modeled in an FDA-supported SEND Implementation Guide version. The FDA Data Standards Catalog, which can be found on the Study Data Standards Resources web page noted above, lists the supported SEND Implementation Guide versions and associated implementation dates.

Although the submission of study data in conformance to the standards listed in the FDA Data Standards Catalog will not be required in studies that started on or before December 17, 2016, CDER strongly encourages IND sponsors to use the FDA supported data standards for the submission of IND applications and marketing applications. The implementation of data standards should occur as early as possible in the product development lifecycle, so that data standards are accounted for in the design, conduct, and analysis of clinical and nonclinical studies. For clinical and nonclinical studies, IND sponsors should include a plan (e.g., in the IND) describing the submission of standardized study data to FDA. This study data standardization plan (see the FDA Study Data Technical Conformance Guide) will assist FDA in identifying potential data standardization issues early in the development program.

If you have not previously submitted an eCTD submission or standardized study data, we encourage you to send us samples for validation following the instructions at FDA.gov.[9] For general toxicology, supporting nonclinical toxicokinetic, and carcinogenicity studies, submit data in the Standards for the Exchange of Nonclinical Data (SEND) format. The validation of sample submissions tests conformance to FDA supported electronic submission and data standards; there is no scientific review of content.

The Agency encourages submission of sample data for review before submission of the marketing application. These datasets will be reviewed only for conformance to standards, structure, and format. They will not be reviewed as a part of an application review. These datasets should represent datasets used for the phase 3 trials. The FDA Study Data Technical Conformance Guide[10] (Section 7.2 eCTD Sample Submission pg. 30) includes the link to the instructions for submitting eCTD and sample data to the

[8] http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm
[9] https://www.fda.gov/industry/study-data-standards-resources/study-data-submission-cder-and-cber
[10] https://www.fda.gov/media/88173/download

Agency. The Agency strongly encourages Sponsors to submit standardized sample data using the standards listed in the Data Standards Catalog referenced on the FDA Study Data Standards Resources web site.[11] When submitting sample data sets, clearly identify them as such with **SAMPLE STANDARDIZED DATASETS** on the cover letter of your submission.

Additional information can be found at FDA.gov.[12]

## LABORATORY TEST UNITS FOR CLINICAL TRIALS

CDER strongly encourages IND sponsors to identify the laboratory test units that will be reported in clinical trials that support applications for investigational new drugs and product registration. Although Système International (SI) units may be the standard reporting mechanism globally, dual reporting of a reasonable subset of laboratory tests in U.S. conventional units and SI units might be necessary to minimize conversion needs during review. Identification of units to be used for laboratory tests in clinical trials and solicitation of input from the review divisions should occur as early as possible in the development process. For more information, please see the FDA website entitled Study Data Standards Resources[13].

## PEDIATRIC ASSESSMENTS

As amended by the Food and Drug Administration Safety and Innovation Act (Public Law 112-144, 126 Stat. 993) of July 9, 2012, the Pediatric Research Equity Act (PREA) requires any sponsor who plans to file a marketing application for a drug or biological product (FDCA section 505 or PHSA section 351, respectively) that includes a new active ingredient, new indication, new dosage form, new dosing regimen, and/or new route of administration to submit an initial Pediatric Study Plan (PSP) (21 U.S.C. 355c). The intent of the PSP is to identify needed pediatric studies and begin planning for these studies. The timing and content of an initial PSP, including a template, can be found in the guidance for industry *Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Initial Pediatric Study Plans*.[14]. Review this guidance and the PREA requirements to determine if your application must contain an assessment (pediatric clinical data), waiver request, and/or deferral request (21 U.S.C. 355c).

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[11] https://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm
[12] https://www.fda.gov/industry/study-data-standards-resources/study-data-submission-cder-and-cber
[13] http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm
[14] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pediatric-study-plans-content-and-process-submitting-initial-pediatric-study-plans-and-amended

If you have any questions, you may contact the Division of Pediatric and Maternal Health at [redacted] or email [redacted].

If you have any questions, contact me, at [redacted]

Sincerely,

*{See appended electronic signature page}*

Iram Baig, MS
Regulatory Project Manager
Psychiatry Group
Division of Regulatory Operations for Neuroscience
Office of Regulatory Operations
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**

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/s/

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