IN THE UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF	§	
	§	
	§	Docket No. 22-15
Scheduling 4-OH-DiPT, 5-MeO-AMT,	§	
5-MeO-MiPT, 5-MeO-DET, and DiPT	§	
	§	

PANACEA PLANT SCIENCES MOTION FOR SUMMARY DISPOSITION

Panacea Plant Sciences find fault in the current administrative court hearings regarding the action to schedule 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT, and thus move to have the government attempts to schedule these items overturned and prevented by the tribunal and ask for summary disposition. Panacea Plant Sciences hereby incorporates arguments in the Preliminary Objection and Reply relating to the untimely HHS evaluation.

Panacea Plant Sciences would like to provide evidence in support of Panacea Plant Sciences opposition to the government scheduling actions, the party states as follows:

Factual Background

1. The DEA submitted Docket 688A on levels of controlled substance manufacturing on September 2, 2021. The DEA did not open the comment page on Regulations.gov relating to the docket for more than 2 weeks after the filing. In response Panacea Plant Sciences contacted the DEA and Regulations.gov and alerted them to these facts. Regulations.gov indicated that the DEA was in fact the party which was not making the comment page live for the public as needed by law. In response Panacea Plant Sciences alerted the DEA to this issue and DEA still did not have the comment page operational for more than 24 hours. Panacea Plant Sciences then published a press release informing the public of these facts in order to increase public comment and requests

for DEA action to make the comment page live. Even after DEA made public listing for Docket 688A the agency did not immediately turn on comments and took another day to do so. These facts are documented in a series of communications between David Heldreth/Panacea Plant Sciences and DEA and Regulations.gov which have been submitted with this document as: Exhibits DEA688 1-4.

2. Panacea Plant Sciences on November 4, 2021 filed FOIA requests on DEA records related to DEA drug scheduling actions. The agency declined the FOIA request on December 3, 2021, Panacea responses for the FOIA declination are ongoing. (records included as: Exhibits FOIA 1-3)

3. Panacea Plant Sciences has been working on research with 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, DiPT and other items and was preparing for an international project with Philippe Henry and the company Egret Bioscience which are based in Canada, on developing medical therapies related to compounds such as tryptamines and phenethylamines. 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET and DiPT are some of the targets of that research. Egret and Panacea have been in contact with Health Canada, some of that communication was provided to the DEA on December, 31 of 2021, in order to attempt to smooth over cross border collaboration and shipment of items through customs as we try to expand collaborative research on 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET and DiPT and other compounds. DEA responded without providing clarification on the status or any mention of a pending scheduling attempt. 2 weeks later, on January 14, 2022 the DEA filed the scheduling notice in the federal register and the scheduling process began for 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET and DiPT. (communications contained in: Exhibits DEA Contact 1-2)

4. DEA 8-factor analysis and other documents used in the attempt to control/schedule 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET and DiPT utilize documents which are almost ten years old. The scheduling process was stalled internally—and maybe terminated some time years ago after receiving the 2012 HHS report by an earlier DEA—and was/is not urgent. DEA apparently resurrected the scheduling/control process in response to Panacea Plant Sciences communications on the items and in response to the company's efforts to call attention to the agency's actions and urge transparency and policy change at the agency rather than due to an actual danger of these items.

5. The deaths in the DEA 8-fator analysis occurred with comorbid use of psychiatric medications along with alcohol and the identified tryptamines. As such it is likely that these deaths have very little to do with the tryptamines alone and are either directly due to the use of alcohol and psychiatric medications which present a known danger or from the combination of those items with the drugs. Additionally, the doses and purity of the drugs as used by the individuals was unknown. These factors which led to unknown drug dosing and the polydrug use are due to lack of education and transparency which occur due to the fact that these compounds are already considered illegal for human use under the analog act. As such the public cannot share information directly and openly which leads to unsafe drug use. Additionally, there is little diversion risk from research and development. From the DEA document entitled "Five tryptamines Eight-factor analysis DEA 082021" you can find the below selection which directly states that companies conducting research are NOT involved with the diversion into recreational or related markets. "HHS states in the 2012 reviews that 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeODET, and DiPT are not Food and Drug Administration (FDA)-approved drug products for treatment in the United States and is unaware of any country in which its use is legal. As of June 2020, DEA

remains unaware of any country approving these drugs for medical use. There appear to be no legitimate sources for 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT as marketed drugs (HHS reviews, 2012a-e). The DEA notes that these five tryptamines are available for purchase from legitimate chemical companies because they are used in scientific research. No evidence of diversion is apparent from these companies. As such, this characteristic of abuse potential is not applicable."

6. Hallucinogens/psychedelics are having a revival for their use as medical treatments. This is due to the apparent connection between 5-ht2a agonism and the ability to provide long term relief from and treatment of depression, anxiety, addiction, PTSD and other mental health conditions. The 5ht2a receptor agonism is the mechanism of medical benefit. As such it is intriguing to see DEA Eight-factor analysis use 5ht2a activity and binding levels used as reasons to make these compounds illegal. This same activity is why these compounds do in fact have medical uses. In fact, Field Trip is developing 4-HO-DIPT as a medical drug with the FDA currently.

Argument

7. Panacea Plant Sciences is conducting research on 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET and DiPT directly developing medical treatments. If these compounds are moved to schedule 1 it would require that Panacea Plant Sciences apply for both manufacturing and research licensing from the DEA which would cost thousands of dollars in application costs, and additional security and related infrastructure would cost hundreds of thousands of dollars more in order to come into compliance with DEA rules and regulations at the locations and groups with which Panacea Plant Sciences is working with on these items. It would also cost months and months or years of delays in awaiting DEA approvals as they review applications.

8. Panacea Plant Sciences has provided several examples of reasons and actions the DEA has taken which demonstrate direct responses to Panacea Plant Sciences communications, actions and business interests rather than due to public health or risk of items being looked at. This, along with the stale HHS evaluation, demonstrates that this scheduling process is invalid and should not move forward.

CONCLUSION

For the foregoing reasons, Panacea Plant Sciences requests the Tribunal find fault with the government scheduling process and that is irreparably harmed, that the compounds are being studied for medical use and to summarily dismiss the DEA/government scheduling process for 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT.

Date: April 22, 2022

Respectfully submitted,

/s/ David Heldreth
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For Panacea Plant Sciences

CERTIFICATE OF SERVICE

On April 22, 2022, I served a copy of this motion on via email to the DEA Judicial Mailbox (**ECF-DEA@dea.gov**) and the Government Mailbox at (**dea.registration.litigation@dea.gov**).

/s/ David Heldreth_____