U.S. FOOD & DRUG ADMINISTRATION

Memorandum

From: Michele Mital
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Office of the Center Director, Center for Tobacco Products

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Date: 2022.06.23 08:56:34 -04'00'

To: File

cc: Matt Holman
Director
Office of Science, Center for Tobacco Products

Date: June 23, 2022

Subject: Juul Review

The Office of Science (OS) regularly consults with the Office of the Center Director (OCD) in making regulatory decisions under the Tobacco Control Act, including when review raises novel and complex regulatory questions, such as application of the statute's unique public health standard to a new category of products. Consistent with this longstanding practice, during consultations related to the Juul application bundle [Submission tracking numbers PM0000864, PM0000872, PM0000874, PM0000876, PM0000878, PM0000879], OCD advised OS that OCD would review any conclusions reached by OS for this bundle before those conclusions became a final agency decision. This includes conclusions regarding the risks and the potential benefits of the products to the population as a whole, including users and non-users.

The Technical Project Lead (TPL) has finished reviewing the pending Juul application bundle and has advised OCD that an MDO should be issued because of toxicological deficiencies, which are described in the TPL Review (Toxicology) and the relevant disciplinary reviews. The TPL has also advised OCD in a separate memo, TPL Review (Additional Disciplines), that OS has completed other (non-toxicology) discipline reviews.

OCD initiated review of the conclusions reached by OS. OCD completed review of the TPL Review (Toxicology) and hereby concurs with its conclusions. Because OCD concurs that the toxicological issues are dispositive of the applications, it is not necessary for OCD to review and resolve (and thus CTP has not resolved) any other aspects of the applications.

OS and OCD agree that CTP should issue an MDO for the application bundle on the basis of the toxicological deficiencies alone. Therefore, the discipline reviews and related conclusions in the separate memo, TPL Review (Additional Disciplines), have not been adopted by OCD and do

not reflect complete agency consideration or a final agency decision. In addition, the MDO letter should indicate that the list of deficiencies supporting the denial is not necessarily exhaustive. Whether further deficiencies may be found would not change the current conclusion that the applicant has not demonstrated that marketing of these products is appropriate for the protection of the public health.