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Memorandum

To:	File	
From:	Benjamin J. Apelberg, Ph.D. Deputy Director Office of Science	Digitally signed by Benjamin Apelberg -S Date: 2022.04.17 22:17:42 -04'00'
Through:	Cristi Stark, M.S. Director Division of Regulatory Project Management Office of Science	Digitally signed by Cristi L. Stark -S Date: 2022.04.25 17:05:36 -04'00'
	Matthew Holman, Ph.D. Director Office of Science	Digitally signed by Matthew R. Holman -S Date: 2022.04.26 07:00:52 -04'00'
	Emily Talbert Lead Health Communications Officer Office of Health Communication and Education	Emily Talbert -S Digitally signed by Emily Talbert -S Date: 2022.05.02 12:03:26 -04'00'
	Kathleen Crosby Director Office of Health Communication and Education	Kathleen M. Crosby -S Digitally signed by Kathleen M. Crosby -S Date: 2022.05.02 16:00:05 -04'00'
Subject:	Addendum to Guidelines for Office of Health Communication and Education (OHCE) Consult for PMTA Marketing Information Review and Evaluation	

Background

OS and OHCE previously finalized a memo describing the process and expectations by which OS would consult OHCE for their review and evaluation of Marketing Information within PMTA submissions ([“Guidelines for Office of Health Communication and Education \(OHCE\) Consult for PMTA Marketing Information Review and Evaluation”, August 2020](#)). This addendum serves to remove Social Science from the workflow. The scope of OHCE review and evaluation has not been modified. This change is to improve efficiency in the scientific review process.

Discussion

Previously, Social Science would identify the need for an OHCE consult if Marketing Information was present in a PMTA. However, the PMTA Final Rule (“Premarket Tobacco Product Applications and Recordkeeping Requirements”, effective November 2021), requires all PMTAs to contain marketing plans (21 CFR 1114.7); therefore, we now expect an OHCE consult is needed for all standard PMTAs.

The workflow for OHCE consult is revised as follows:

1. RHPM will generate and send the consult request to OHCE (week 1 of scientific review).
2. OHCE will provide the memo, addressed to the TPL, to the TPL and RHPM upon completion (week 3 of scientific review).
3. The TPL will pull relevant information from the memo directly into their TPL review.
4. The TPL will inform OHCE when the memo can be finalized, signed, and posted to the database.

OHCE will upload their finalized memo to Rhapsody.