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Memorandum

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Subject: Guidelines for Office of Health Communication and Education (OHCE) Consult for PMTA Marketing Information Review and Evaluation

Background

During substantive scientific review (scientific review) for the premarket tobacco product application (PMTA) pathway, an OHCE consult will be requested by the OS Social Science reviewer through the Regulatory Health Project Manager (RHPM), with concurrence from the Technical Project Lead (TPL), to review and evaluate the marketing plan information in a PMTA. Marketing plan information could include a high-level description of several key aspects of the applicant's plans to market their product for at least the first year after receiving an order, including the intended target audience, how they applicant would target their intended audience and what other groups would foreseeably be exposed, and how exposure would be limited for individuals below the legal purchasing age. Additional information could include: the types and sources of data, technologies, and methodologies the applicant would use to develop, implement, and track targeted paid media plans; the marketing channels and tactics an applicant expects to use; and actions the applicant would take to limit youth exposure to the marketing.

The presence or absence of marketing plan information will be identified during the first two days of PMTA scientific review by the assigned Social Science reviewer. If the reviewer determines that marketing plan information is present and that an OHCE consult is necessary, the Social Science reviewer will draft a consult containing questions to address the adequacy of the plans, the intended audience, and scope. The consult request will be submitted to the RHPM by the Social Science reviewer. The RHPM will then submit the request to OHCE within one calendar day. A finalized memo will be provided to the RHPM by OHCE within 14 calendar days of receipt of the consult request. The Social Scientist, TPL, and other review team members will consider the information provided by the OHCE consult during scientific review and incorporate into their reviews and recommendation as appropriate

Guidelines

- The Social Science reviewer will initially identify the presence or absence of marketing plan information in the application.
 - If marketing plan information is present, after discussion with their branch leadership, the reviewer will determine the need for an OHCE consult based on the application's contents.
 - If a consult is necessary, the consult request will be submitted to the RHPM within two calendar days of the start of scientific review.
 - The RHPM will submit the consult request to OHCE within one day of receipt of the request from the Social Science reviewer.
 - The RHPM is responsible for submitting the consult to OHCE, facilitating communication between OHCE and OS, including any meetings, and confirming receipt of the final OHCE memo.
 - Social Science will continue to conduct the primary review of the impact of the products' labels, labeling, and advertising (LLA) on understanding, perceptions, and intentions to use the product.
- Certain situations may arise where the Social Science reviewer determines that an OHCE consult is not needed, even if a marketing plan is present, including but not limited to:
 - The marketing plan is identical to another application for which a consult already exists
 - Insufficient information on the marketing plan is contained in the application
 - The application is accepted during filing review, however the TPL determines the application is grossly deficient (consult could then occur during second round of review, which may require a turnaround quicker than 14 days)
- In general, OHCE's scope of review should include assessing the extent to which the marketing plan information submitted by the applicant: 1) describes a reasonable approach to targeting the applicant's intended users of the product(s); and 2) describes measures to restrict youth access to the product(s) and limit youth exposure to the products' labeling, advertising, marketing, and promotion.
 - OHCE will assess the intended labeling, advertising, marketing, promotion, and other consumer-directed activities provided by the applicant in the context of the applicant's marketing plan information.
 - OHCE's consult will formulate conclusions on any potential concerns with the planned measures and provide recommendations for proposed restrictions to mitigate potential

- concerns. This assessment will inform Social Science conclusions regarding the adequacy of these plans, considering the totality of information in the application.
- OHCE will provide a recommendation based on their assessment of the appropriateness or strength of any planned measures described in the application.
 - OHCE's review assumes that any granted orders for the product(s) would include, to the extent applicable and appropriate, any current set of postmarket requirements and restrictions in recent marketing orders. To the extent that an applicant is proposing an approach that is more or is less stringent than these requirements, it will be noted in OHCE's review.
 - OHCE will include high-level recommendations for postmarket requirements/restrictions based on the application information submitted. The development of additional recommendations for postmarket requirements/restrictions are outside the scope of OHCE's review during the scientific review phase. OHCE does not plan on developing additional requirements/restrictions beyond those proposed by the applicant during the scientific review phase.
- Within the Social Science scientific review, reference to the consult or language directly from the consult may be incorporated, as appropriate. The consult memo should not be inserted, as a whole, into the Social Science review nor included as an Appendix to the Social Science review. The consult will, however, be included in the administrative record for the PMTA.
 - In the event that CTP decides to move forward with authorizing a PMTA where OHCE has identified marketing-related concerns, OHCE should be re-engaged to help develop the most appropriate requirements/restrictions to include in the marketing granted order. OHCE should be re-consulted after the preliminary assessment meeting and provide requirements/restrictions within an agreed upon time period.

Process

1. The Social Science reviewer drafts the consult request and submits it by email to the RHPM, including DRPM-IO on the email within two days of scientific review kickoff. The consult email request should clearly state the following:
 - Requestor information (i.e., Social Science reviewer);
 - Applicant name, product STN(s), and product name(s);
 - The specific section(s) or page number(s) of the application where information on marketing plans may be found in the application or in cross-referenced STN(s);
 - Requested completion date (OHCE standard is 14 calendar days) and justification if consult request needs to be expediated (less than 14 days); and
 - Any substantive review items noted by the Social Science Reviewer (not required given the short timeline to submit the request, however the reviewer may notice specific items that they could flag for OHCE to review).
2. The RHPM submits the consult request by email on behalf of the Office Science (OS) to the OHCE Marketing Plan Review Team distribution email list one day after receiving the request from the Social Science reviewer. The TPL and the primary Social Science reviewer should be included on the consult request and the finalized consult memo communications.
3. The RHPM will facilitate communication between OS and OHCE to verify the request has been clearly communicated, encourage continued communication as the review progresses to discuss

issues that arise, and ensure the consult memo includes a response to each element. The RHPM will be responsible for archival of the OHCE memo.

4. OHCE consults will be completed in the form of a memo to the RHPM within 14 calendar days of the consult request. Consult memos will be signed by the author and cleared through a second-level signatory. The memo will then be sent back to the RHPM, TPL, and Social Science reviewer and added to the administrative record for the PMTA.