Meeting of the Tobacco Products Scientific Advisory Committee

May 18, 2023

TPSAC Committee Members (Voting)
Cristine Delnevo, Ph.D., M.P.H. Chair
Mignonne C. Guy, Ph.D.
Sven-Eric Jordt, Ph.D. +
Adam Leventhal, Ph.D.
Lucy Popova, Ph.D.
Risa Robinson, Ph.D.
Scout, Ph.D., M.A.*
Dona Upson, M.D., M.A.**

Industry Representatives (Non-Voting)
William Andy Bailey, Ph.D. (Growers)
Maria Gogova, Ph.D., M.D. (Manufacturers)
David Johnson, Ph.D. (Small Business)

Ex-Officio Participants (Non-Voting)
Alberta Becenti, M.P.H. (IHS)
Deirdre Lawrence Kittner, Ph.D., M.P.H. (CDC)
Lisa Postow, Ph.D. (NIH)

FDA Administrative Staff
CAPT Serina A. Hunter-Thomas, M.S.A., R.N.
Janice O'Connor

FDA Participants
Matthew Brenner, J.D. +
Ele Ibarra-Pratt, R.N., M.P.H.
Diana Kaneva, J.D.
Brian King, Ph.D., M.P.H.
Dylan Leischow, M.A.
Cristina McLaughlin
May D. Nelson, J.D., M.P.A.
Sarah Seager Stewart, J.D.
Dale Slavin, Ph.D.
Thomas Sundlof, J.D.
Matthew Walters, Ph.D., M.P.H.
Emil Wang, J.D.

Legend
+ Remote Attendance
* General Public Representative
**State, Local or Federal Gov't. Representative

Tobacco Products Scientific Advisory Committee (TPSAC)

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Tobacco Products (CTP)
FDA White Oak Conference Center
Building 31, Room 1503
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 18, 2023

These summary minutes for the May 18, 2023 Meeting of the Tobacco Products Scientific Advisory Committee were approved on July 12, 2023.

I certify that I participated in the May 18, 2023 Meeting of the Tobacco Products Scientific Advisory Committee and that these minutes accurately reflect what transpired.

/s/	/s/
Serina A. Hunter-Thomas	Cristine Delnevo, PhD, MPH
Designated Federal Officer	Chair

The Tobacco Products Scientific Advisory Committee (TPSAC) of the Food and Drug Administration, Center for Tobacco Products (CTP) met on May 18, 2023 at the FDA White Oak Conference Center, Building 31, Room 1503, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002. Prior to the meeting, committee members and invited participants were provided copies of the background materials from the FDA. The meeting was called to order by Cristine Delnevo, Ph.D., M.P.H. (Chair); housekeeping items and the conflict of interest statement was read into the record by CAPT Serina Hunter-Thomas, M.S.A, R.N. (Designated Federal Officer). There were approximately 30 persons in attendance. There were a total of three speakers for the Open Public Hearing session.

Agenda: *On May 18, 2023, the committee met in open session to discuss the proposed Requirements for Tobacco Products Manufacturing Practice (TPMP) rule.*

After the housekeeping and COI statements were read by the DFO, the presentation began, starting with RDML Emil Wang providing the FDA presentation. At the completion of RDML Wang's presentation, the meeting proceeded on to the Open Public Hearing (OPH) session. One OPH speaker was present while the two other OPH speakers provided their comment virtually.

Following the open public hearing, there was a brief morning break. At the end of the break the meeting reconvened and the committee members were encouraged to ask clarifying questions of FDA. After the period of clarifying questions and pre-committee discussion comments, the meeting proceeded on to a lunch break. After the lunch break, the committee reconvened to continue discussion, and more specifically to address the five discussion questions posed to the committee.

The discussion questions and committee comments/responses were as follows:

1. The proposed scope of the rule covers finished and bulk tobacco product manufacturers, including specification developers. Does the committee have any recommendations on the scope, including expanding the scope?

    - Pre-existing tobacco products should not be excluded from the proposed rule
    - Inclusion of retailers in the proposed rule for Consideration of establishing a shelf life to address expired products for ENDS and other tobacco products, e.g., Smokeless Tobacco (SLT)

2. Does the committee have any recommendations or comments on the "umbrella" approach that proposes requirements in flexible terms to enable manufacturers who are subject to the rule to establish procedures that are appropriate for their specific products and operations?

    - Provide guidance to industry such as best practices and/or model examples for specific manufacturers

- In general, support but request consideration so as to not stifle innovation of new or future products

3. Does the committee have any recommendations on the product specifications that FDA proposes to require in the master manufacturing record (MMR)?

    - MMR requirements should include guidance on preferred units of measure which are specific for the component and be stated in such a way to be able to compare components across products
    - MMR documents should be made available to the public and for the purposes of independent research
    - MMR should consider the reality that constituents in the unpuffed and unheated ENDS product can be quite different than the constituents in the emissions
    - Implement standardization of nicotine units across all products, for example, milligram per milliliter by total nicotine contained in the container or package
    - Regulate how much nicotine can be sold in one container or manufactured and put in one container

    Re: <u>Labeling and packaging considerations</u>:

        - More consistent labeling across products, i.e., standardization
        - Research on what kind of labeling is better understood for low literacy and priority populations
        - Child-proof packaging on products that have high nicotine levels,
        - For engineered products, that may have issues to sunlight exposure, such as ENDS, recommend opaque product packaging
        - Consider prohibiting packaging that may be enticing to youth, such as mimicking candy/gum packages to prevent accidental exposure/ingestion

4. Does the committee have any recommendations on the proposed design and development activities and risk management process to control risks associated with finished and bulk tobacco product and its production processes, packing, and storage?

    - Recommend applying design and development activities and risk management process for ENDS and pre-existing tobacco products (to include any available documentation, although such firms do not need to recreate information that is not available)
    - Recommend the establishment of and compliance with a track and tracing system, either on behalf of the manufacturers or the FDA or

both

- Recommend clear guidance on adverse events, such as what is an adverse event and establishing a timeline to report it
- Consider including in the track and trace system not only adverse events but also establish a way to have a record of best practices for manufacturers
- Research types of testing that would be needed in order to maintain quality assurance and prevent deviations from the products being manufactured from their intended specifications
- Recommend risk assessment results be available to the public
- Recommend recycling programs for ENDS to help minimize the risks related to batteries. The product used by the consumer can be taken back by the manufacturers and disassembled and discarded accordingly so they cannot cause any explosions and the components can be discarded in an environmentally friendly manner

5. Does the committee have any additional recommendations on the requirements of the proposed rule?

- The timeline in the final rule should be compressed, effective within 1 year
- FDA should require design verification and validation, design approval, and design transfer to establish a benchmark for pre-existing tobacco products.
- Support additional research on nicotine delivery of different products
- Recommend additional studies on racemic and synthetic derived nicotine
- Consider a potential follow-up meeting that would include scientists from FDA and other scientists to provide more information on what types of chemicals or tests would be included in the guidance to industry. In other words, guidance on what manufacturers should test for to ensure benchmarks are being met.
- Recommend regular guidance updates to reflect updates science and the identification of new constituents
- Recommend amending the language from “not normally associated” to “not inherent”
- Allow room for smaller manufacturers to apply for exemptions with some sections as opposed to exempting complete groups of this rule
- Software controller is a key aspect of nicotine delivery in ENDS and should be a key component in product regulation and transparency
- Consider software controls, heating element feedback, such as maximum coil temperature and power on/off criteria in the proposed rule
- Mixed recommendation regarding an exemption for premium cigars. Support for exemption could result in allocating resources to maximize the impact on public health Opposition for exemption pointed to potential for cigar products to modifying their characteristics to obtain exemption.

- The TPMP provides a petition process for exemption which can be pursued by premium cigar manufacturers.
- Do not want tobacco industry indicating that their adherence to this proposed rule in any way constitutes a healthier product, therefore, recommend FDA create language along the lines of "this product conforms to FDA's manufacturing specifications" or something like that so as to not come across as being healthy.
- If pre-existing tobacco product, recommend submitting final product specifications to make sure documents are not being created that didn't exist, and to establish a baseline by which to figure out if a document is in or out of compliance
- FDA should consider the different areas where reporting might exist that need to be monitored in order to understand the full public impact
- Recommend that EVALI and other health problems that come up be looked at immediately and that both the public and health/medical professions be informed right away

After the committee provided closing summary statements, the Chair invited FDA to provide final comments. After final comments from RDML Emil Wang, the TPSAC meeting was adjourned.

Additional information and details may be obtained from the transcript and the recording of the webcast of the meeting that may be viewed via the following YouTube link:

https://www.youtube.com/watch?v=0xjMFa11tHA