

Demonstrating “Appropriate for the Protection of Public Health” (APPH)

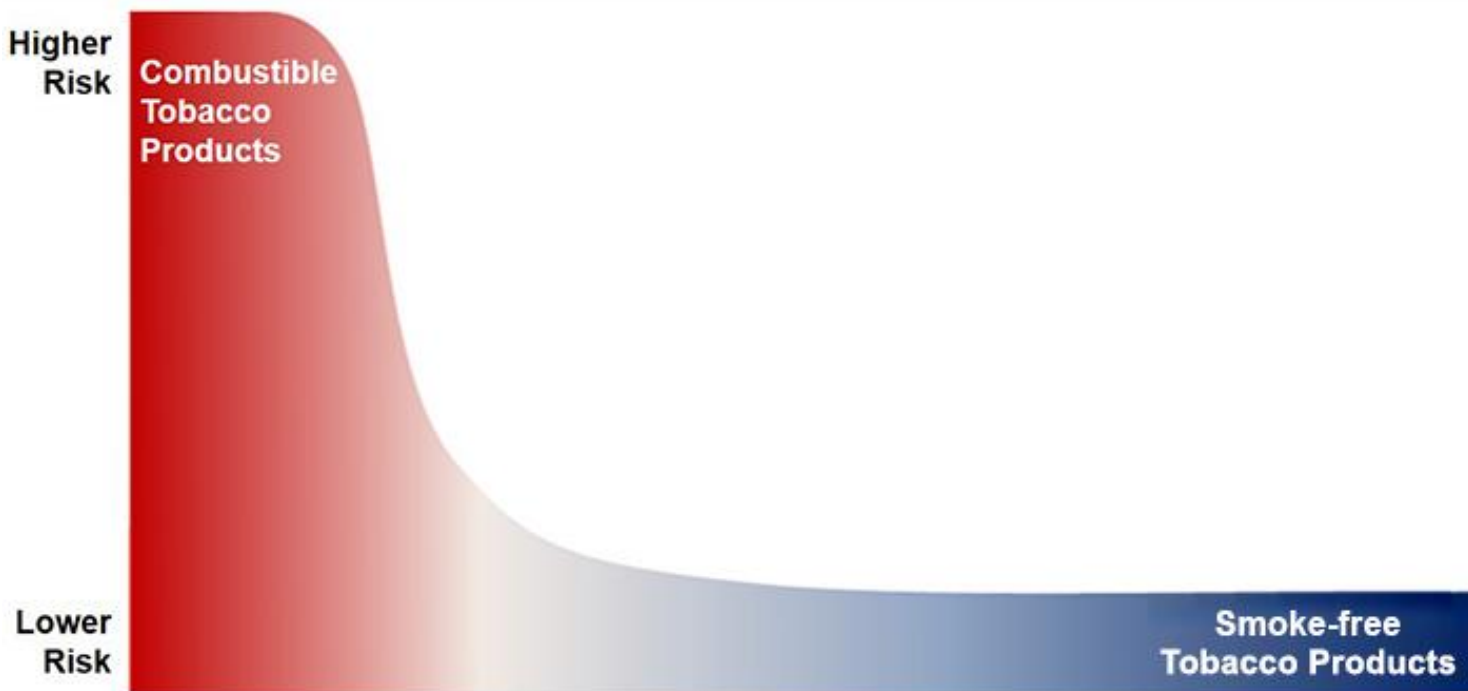
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Regulatory Affairs

Risk Cliff Between Combustible & Smoke-free Tobacco



Adapted from Nutt, et. al Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach. Eur. Addict Res 2014; 20:218-225.

Scientific Framework for Evaluating Reduced-Harm Tobacco Products

CONSTITUENT REDUCTION



THE PRODUCT

- Chemistry Manufacturing and Controls
- Product Stability
- Chemical Characterization

INDIVIDUAL RISK REDUCTION



EXPOSURE and HEALTH RISK

- Toxicology & Risk Assessment
- Health risk assessment (absolute and relative)
- Human Studies

POPULATION HARM REDUCTION



IMPACT on the POPULATION

- Risk perceptions (absolute and relative)
- Impact of product on users
- Impact on non-users
- Overall impact on the population
- Environmental Assessment

Recent PMTA:

Oral Tobacco Derived Nicotine Products (OTDN)

- On May 15th, 2020, we submitted PMTAs for a portfolio of OTDN products
- The products, on![®] Nicotine Pouches are tobacco leaf-free and only contain pharmaceutical grade tobacco-derived nicotine and non-tobacco ingredients
- Many of the ingredients used in on![®] Nicotine Pouches are designated as “Generally Recognized as Safe” (GRAS) for use in foods.*



Nicotine pouches

*While the GRAS status is limited to food, the scientific data and assessments used to review food ingredients inform our understanding of the possible toxicity of chemicals contained in the candidate products which are used orally.

Integration of Multiple Lines of Evidence to Demonstrate that on!® Nicotine Pouches are APPH*

- ✓ HPHC reduced / eliminated
- ✓ Switching completely will substantially reduce exposure to most HPHCs which should reduce smoking related disease risks
- ✓ Abuse potential lower or comparable to cigarettes or ST
- ✓ Adult tobacco users switch completely
- ✓ Cigarette or ST consumption reduced by >50%
- ✓ Adult tobacco users perceive products not risk-free
- ✓ Low likelihood of use in nonusers, including youth



Net Population Benefit

APPH

*Appropriate for the Protection of Public Health

Accelerating APPH Determinations for Reduced Risk Products



Products Standards



Accelerated review times
for supplemental PMTAs



Viable pathway(s) for
minor product changes