FDA Regulatory Process for Vapes and E-Cigarettes

Vape/E-Cigarette Regulatory Working Group

Presented by LSO Staff: Ellen Upton, Ph.D.
Science and Technology Fellow &
Kelci Karl-Robinson, Revenue Analyst

FDA Authorization of E-Cigarettes

- Tobacco products are **authorized** not **approved** indicating that they do not follow the same "safe and effective standard for evaluating medical products"

- A marketing authorization does not indicate that the tobacco product is either safe or "approved." It means that the manufacturer has complied with the requirements under the law to bring its product to market.

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Source: FDA Facts about e-cigarettes

Premarket Tobacco Product Applications

- Tobacco products are assessed by the FDA Center for Tobacco Products Office of Science
- A Premarket Tobacco Product Application (PMTA) must be submitted for any E-Cigarette manufacturer to comply with FDA rules stated in the Federal Food, Drug, and Cosmetic Act (FD&C Act).

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Source: FDA website "Premarket Tobacco Product Applications "

PMTA Considerations by the FDA

- A PMTA must provide scientific data that demonstrates a product is appropriate for the protection of public health. In order to reach such a decision and to authorize marketing, FDA considers (per section 910(c)(4) FD&C Act), among other things:
  - Risks and benefits to the population as a whole, including people who would use the proposed new tobacco product as well as nonusers
  - Whether people who currently use any tobacco product would be more or less likely to stop using such products if the proposed new tobacco product were available
  - Whether people who currently do not use any tobacco products would be more or less likely to begin using tobacco products if the new product were available
  - The methods, facilities, and controls used to manufacture, process, and pack the new tobacco product

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Source: FDA website "Premarket Tobacco Product Applications "

Preparing and Submitting a PMTA

- E-Cigarette manufacturers must file a premarket tobacco product application or PMTA
- PMTAs must include:
  - General information
  - Descriptive information
  - Product samples
  - Labeling and description of marketing plans
  - Statement of compliance with 21 CFR part 25
  - Health risk investigations
  - Summary
  - Product formulation
  - Manufacturing
  - The effect on the population as a whole
  - Certification statement

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Source: FDA website "Premarket Tobacco Product Applications "

The Tobacco Product Authorization Process

- Phase 0 – Voluntary Presubmission meetings with the FDA
- Application Submitted
- Phase 1 – Acceptance Review: making sure the product is a tobacco product and meets all the application requirements
- Phase 2 – Filing Review: determining if the application contains all required information
- Phase 3 – Application Review: FDA evaluation of scientific information and data in an application
- Phase 4 – Post market reporting: Marketing Order ether granted or denied

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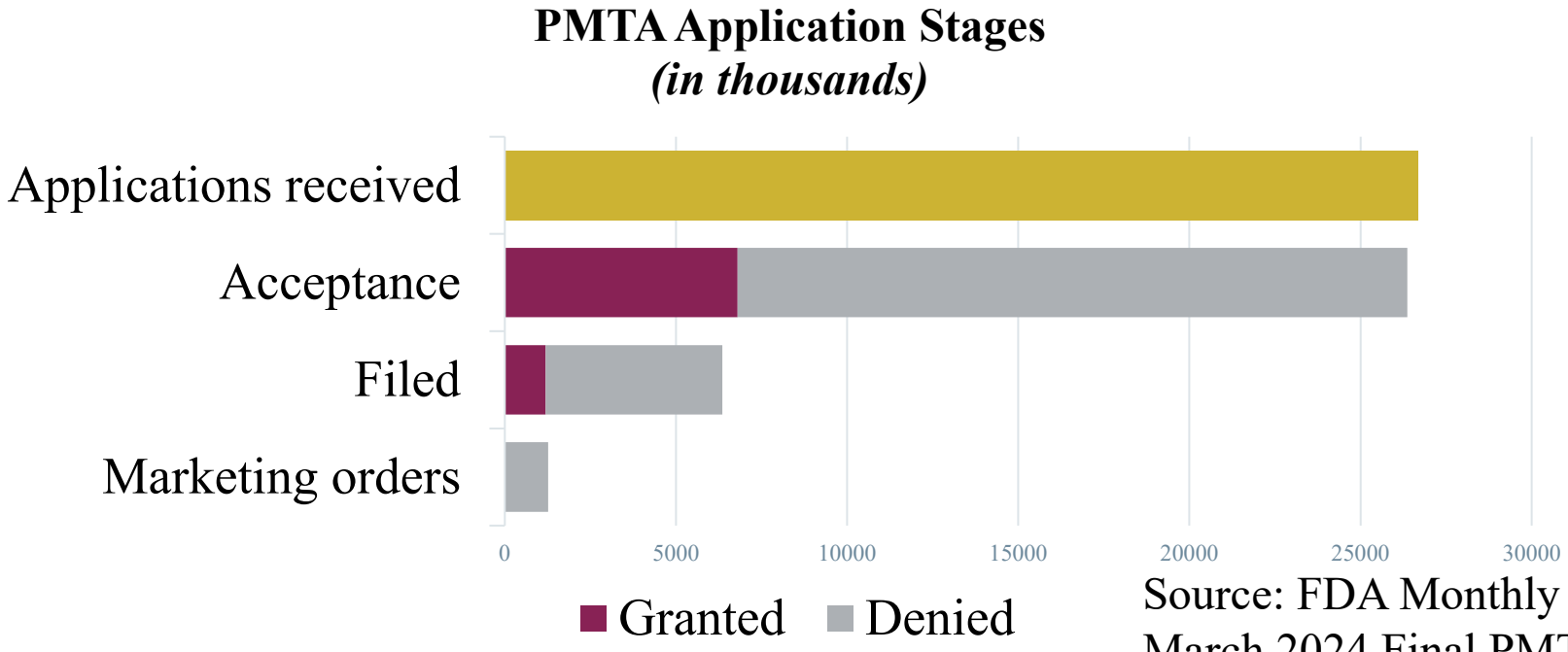
Source: FDA website "Premarket Tobacco Product Applications "

The process by the numbers, as of March 2024

- E-Cigarette Applications Received since 2020 – 26,695,013
- Phase 1 – Acceptance Review: 6,798,953 accepted – 19,564,348 denied
- Phase 2 – Filing Review: 1,191,007 accepted – 5,161,595 denied
- Phase 4 – Post market reporting: 23 granted – 1,263,854 denied



Source: FDA Monthly Metrics March 2024 Final PMTA

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FDA Retail Inspection Program in Idaho

- FDA contracts with state government agencies when feasible to assist with conducting inspections of retail establishments.
- FDA had contracts in place with the Idaho Department of Health and Welfare from 2010 through 2018
- From 2018 to today FDA commissioned inspectors have performed retail inspections in Idaho through third-party contracts with private companies
  - Contracts are awarded based on the offeror's ability to demonstrate their capabilities to meet the requirements of the Federal Acquisition Regulations and do the work as prescribed by the FDA, the amount of work proposed, and costs associated with the proposed work
  - The offeror must also be able to pay for the expenses up-front and receive payment from the government after expenses have been incurred
- Over 17,000 tobacco retail inspections have been conducted in Idaho since the start of the FDA program
- The FDA has issued over 930 warning letters, 130 Civil Money Penalty complaints and one no-tobacco-sale order (NTSO)

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Source: Bria Martin, MPH – Public Health Analyst, Center for Tobacco Products: Stakeholder Relations Office

Other FDA Resources

- FDA Center for Tobacco Products Office of Science
- Premarket Tobacco Product Marketing Granted Orders | FDA
  - Documents (e.g., order letters, decision summaries) associated with Premarket Tobacco Product Marketing Granted Orders
- Searchable Tobacco Products Database
- FDA Facts about e-cigarettes
  - Difference between authorization and approval
- FDA Monthly Metrics March 2024 Final PMTA

Questions?

Ellen Upton, Ph.D.
Science and Technology Fellow
(208) 334-4858
eupton@lso.idaho.gov

Kelci Karl-Robinson
Revenue Analyst
(208) 332-1286
kkarlrobinson@lso.idaho.gov

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