

# EXHIBIT 6

# UPDATES FROM FDA'S CENTER FOR TOBACCO PRODUCTS

*Mitch Zeller, J.D.*  
*Director, FDA Center for Tobacco Products*

*Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.*

## FDA'S TOBACCO AUTHORITIES

- The Tobacco Control Act—passed in 2009—gave FDA im cigarettes, smokeless tobacco, cigarette tobacco, and roll
- When FDA's "Deeming Rule" went into effect on Aug. 8, 2 to cover e-cigarettes and all other electronic nicotine deliv tobacco, nicotine gels, and hookah tobacco
- As a result, deemed products are now subject to the same Control Act that apply to cigarettes, smokeless tobacco, ci own tobacco
  - This includes the requirement that **a new tobacco product m authorization** from FDA to be legally marketed

## REVIEW PROGRESS

- FDA has taken action **on more than 98% of the over 6.5** submitted applications. As of Oct. 13, this includes:
  - Completing acceptance review for all applications submitted b resulted in issuing refuse to accept (RTA) letters to **more than**
  - Completing filing review for almost all timely submitted PMTAs (RTF) letter to a single company for PMTAs associated with **a**
  - Issuing Substantial Equivalence (SE) marketing orders covering
  - Issuing Exemption from SE marketing orders covering more th
  - Issuing **marketing denial orders** (MDOs) for more than **1 mil** products
  - Issuing marketing granted orders for **3 new tobacco product**

## AUTHORIZATION OF ENDS PRODUCTS THROUGH THE PMTA PATHWAY

- On Oct. 12, **FDA authorized the marketing of three new** the first set of ENDS products ever to be authorized by FDA
- R.J. Reynolds (RJR) Vapor Company submitted data that flavored products **could benefit addicted adult smokers** either completely or with a significant reduction in cigarette their exposure to harmful chemicals
- Additionally, FDA considered the risks and benefits to the determined the **potential benefits to smokers outweigh**
- FDA also issued **10 MDOs for RJR's flavored Vuse Solo**

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