U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

FDA News Release

FDA issues orders that will stop further U.S. sale and distribution of four R.J. Reynolds Tobacco Company cigarette products

For Immediate Release

September 15, 2015

Release

Español (/NewsEvents/Newsroom/ComunicadosdePrensa/ucm462684.htm)

Today the U.S. Food and Drug Administration issued orders that will stop the further sale and distribution of four currently marketed R.J. Reynolds Tobacco Company cigarette products – including its Camel Crush Bold brand – because the company's submissions for these products did not meet requirements set forth in the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The FDA's evaluation found that Camel Crush Bold, Pall Mall Deep Set Recessed Filter, Pall Mall Deep Set Recessed Filter Menthol and Vantage Tech 13 cigarettes were not substantially equivalent (NSE) to their respective "predicate" products (i.e., products that were commercially marketed as of Feb. 15, 2007) as identified by the manufacturer. More specifically, the agency concluded the products have different characteristics than the predicate products and that the manufacturer failed to show that the new products do not raise different questions of public health when compared to them. Consequently, at this time, these products can no longer be sold, distributed, imported or marketed in interstate commerce.

“These decisions were based on a rigorous, science-based review designed to protect the public from the harms caused by tobacco use,” said Mitch Zeller, J.D., director of the FDA’s Center for Tobacco Products. “The agency will continue to review product submissions and exercise its legal authority and consumer protection duty to remove products from the market when they fail to meet the public health bar set forth under law.”

The products receiving NSE orders entered the market during a provisional period established by the Family Smoking Prevention and Tobacco Control Act of 2009. As part of the provisional period, the company had to submit a substantial equivalence (SE) application to the FDA by March 22, 2011, in order for the products to remain on the market. The FDA reviews product submissions under this pathway to determine whether the product is substantially equivalent to a valid predicate product. Among other reasons, if a company fails to provide the necessary information to show that its product is substantially equivalent to a valid predicate product, the FDA has the authority to find a product not substantially equivalent.

The scientific basis for these four decisions include a failure to demonstrate that increased yields of harmful or potentially harmful constituents, higher levels of menthol, and/or the addition of new ingredients in the currently marketed products – when compared to the predicate products – do not raise different questions of public health.

In the case of Camel Crush Bold, a failure to demonstrate that the addition of a menthol capsule in the filter did not affect consumer perception and use also contributed to the decision.

When the FDA issues an NSE order, the tobacco product in inventory, including at a retail location, becomes adulterated and misbranded. As a result, it is illegal to sell or distribute the product in interstate commerce, or sell or distribute the product received from interstate commerce. Doing so may result in the FDA initiating enforcement action, including seizure, without further notice.

Recognizing that retailers may have limited options for disposing of products in their current inventories, the FDA does not intend to take enforcement action for 30 days on previously purchased products that a retailer has in its inventory. This policy is further outlined in a recently finalized guidance. Importantly, the policy does not apply to inventory purchased by retailers after the date of the order. Retailers are encouraged to contact their supplier or manufacturer to discuss possible options for existing inventories at specific retailer locations.

Failure to obey federal tobacco product laws may result in the FDA initiating further action without notice, including, but not limited to, civil money penalties, no-tobacco-sale orders, criminal prosecution, seizure, and/or injunction.

Consumers and other interested parties can report a potential tobacco-related violation of the FD&C Act, including continued sale or distribution of the four products in the United States, by using the FDA's **Potential Tobacco Product Violation Reporting Form (https://www.accessdata.fda.gov/scripts/ptvr/index.cfm)**.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

Inquiries

Media

Michael Felberbaum (mailto:michael.felberbaum@fda.hhs.gov)
240-402-9548

Consumers

888-INFO-FDA

Related Information

- **Misbranded and Adulterated NSE Tobacco Products web page (/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm371765.htm)**
- **Tobacco Product Marketing Orders web page (/TobaccoProducts/Labeling/MarketingandAdvertising/ucm339928.htm)**
- **Summary of Not Substantially Equivalent Determinations (PDF - 28KB) (/downloads/TobaccoProducts/Labeling/MarketingandAdvertising/UCM462409.pdf)**
- **Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent (/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm386625.htm)**

Follow FDA

- Follow @US_FDA (https://twitter.com/US_FDA) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
- Follow FDA (https://www.facebook.com/FDA) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
- Follow @FDAmedia (https://twitter.com/FDAMedia) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)

More in Press Announcements (/NewsEvents/Newsroom/PressAnnouncements/default.htm)

2014 (/NewsEvents/Newsroom/PressAnnouncements/2014/default.htm)

2013 (/NewsEvents/Newsroom/PressAnnouncements/2013/default.htm)