Dockets Management Staff (HFA-305) ID: LFG-2018-0025

Food and Drug Administration

5630 Fishers Lane, Room# 1061

Rockville, MD, 20852

Sent via: Mail

October 16th, 2018

Re: Docket Number, FDA-2017-N-4678

Modified Risk Tobacco Product Applications: Applications for Six Camel Snus Smokeless Tobacco Products Submitted by R.J. Reynolds Tobacco Company

Dear Food and Drug Administration,

I am submitting this comment to the Food and Drug Administration is regard and pertaining to Docket Number: FDA-2017-N-4678. As you already know, this docket number pertains "Modified Risk Tobacco Product Applications: Applications for Six Camel Snus Smokeless Tobacco Products Submitted by R.J. Reynolds Tobacco Company." It should be noted that Section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387k) addresses the marketing and distribution of modified risk tobacco products (MRTPs). MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Section 911(a) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any MRTP unless an order issued by FDA under section 911(g) of the FD&C Act is effective with respect to such product. Section 911(d) of the FD&C Act describes the information that must be included in an MRTPA, which must be filed and evaluated by FDA before an applicant can receive an order from FDA. FDA is required by section 911(e) of the FD&C Act to make an MRTPA available to the public (except for matters in the application that are trade secrets or otherwise confidential commercial information) and to request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying the application. The determination of whether an order is appropriate under section 911(g) of the FD&C Act is based on the scientific information submitted by the applicant as well as the scientific evidence and other information that is made available to the Food and Drug Administration, including through public comments.

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application and on the label, labeling, and advertising accompanying the application. The determination of whether an order is appropriate under section 911(g) of the FD&C Act is based on the scientific information submitted by the applicant as well as the scientific evidence and other information that is made available to the Agency, including through public comments. Section 911(g) of the FD&C Act describes the demonstrations applicants must make to obtain an order from FDA under either section 911(g)(1) or (2). The applicant, R.J. Reynolds Tobacco Co., is seeking orders under section 911(g)(1) for each of the 6 products that are the subject of the submitted MRTPAs. A person seeking an order under section 911(g)(1) of the FD&C Act must show that the tobacco product, as it is actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and will benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Section 911(g)(4) of the FD&C Act describes factors that FDA must take into account in evaluating whether a tobacco product benefits the health of individuals and the population as a whole.

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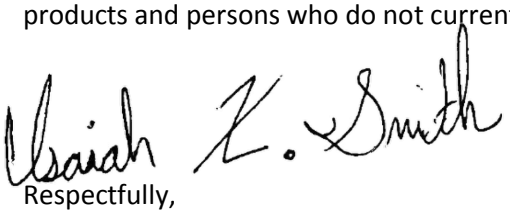
The Food and Drug Administration has issued a notice to inform the public that the MRTPAs for the following products submitted by the applicant, R.J. Reynolds Tobacco Co., have been filed and are being made available for public comments:

- MR0000068: Camel Snus Frost
- MR0000069: Camel Snus Frost Large

- MR0000070: Camel Snus Mellow
- MR0000071: Camel Snus Mint
- MR0000072: Camel Snus Robust
- MR0000073: Camel Snus Winterchill

Since the applicant, R.J. Reynolds Tobacco Co., is seeking orders under section 911(g)(1) for each of the 6 products that are the subject of the submitted MRTPAs, I would like it to be reiterated to you that under section 911(g)(1) of the FD&C Act, the applicant must show that the tobacco product, as it is actually used by consumers, will significantly reduce harm and that the risk of tobacco-related disease to individual tobacco users and will benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Section 911(g)(4) of the FD&C Act describes factors that the Food and Drug Administration must take into account in evaluating whether a tobacco product benefits the health of individuals and the population as a whole. Therefore as far as this docket number is concerned, I would urge the Food and Drug Administration to approve the request of the applicant if their product, as it is actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and will benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.



Respectfully,

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