CENTER FOR TOBACCO PRODUCTS

October 12, 2018

VIA UPS and Electronic Mail

Mr. Graham Gibson
President
Kandypens Inc.
14255 North 79th Street, Suite #8
Scottsdale, AZ 85260

Submission Tracking Number: TC0003969

Dear Mr. Gibson:

It has come to our attention that Kandypens Inc. may be manufacturing new finished tobacco products including, but not limited to, RUBI without premarket authorization, as required by §910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[1] RUBI appears to meet the definition of a tobacco product as set forth in §201(rr) of the FD&C Act. Although FDA has extended the compliance deadlines for the premarketing requirements for deemed products, FDA's compliance policy applies only to those deemed products that were on the market as of August 8, 2016. FDA has received complaints that Kandypens Inc. may have first commercially marketed RUBI in the United States after August 8, 2016.

Please provide FDA with the following information:

1. For the brand name referenced above, please list all sub-brands under the brand name, including all applicable sizes, flavors, nicotine strengths, and other variations. For each sub-brand, confirm whether you are currently marketing the product in the United States, and the date that the product was first commercially marketed in the United States. FDA suggests that you use a chart similar to the following example to help us understand your response:

Product Name (Brand and Sub-brand)	Currently Marketed (Y/N)	Date Product First Commercially Marketed in U.S.

[1] https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf

2. For each of the products listed above, please provide the following information, as applicable:

    a. Evidence that your product was commercially marketed (other than for test marketing) as of February 15, 2007;[2]

    b. Evidence that your product is a deemed product that was on the market on August 8, 2016, and has not been modified since that date;[3]

    c. Evidence that your product was first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to March 22, 2011, and for which a 905(j) (or substantial equivalence) report was submitted no later than March 22, 2011;[4]

    d. Evidence that FDA has issued an order permitting the marketing of this product; and/or

    e. Evidence, which may include a statement from the firm, that the firm is currently not marketing the above-listed product(s).

We request that a written response be submitted within 30 days of receipt of this letter. The response and any further correspondence regarding this matter should reference the Submission Tracking Number listed above. We encourage you to send your response electronically via the CTP Portal[5] using eSubmitter.[6] However, you may also send your response by mail to our Document Control Center:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
10903 New Hampshire Avenue
Building 71, Room G335
Silver Spring, MD 20993-0002

[2] https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm416495.htm
[3] See "Effective and Compliance Dates Applicable to Retailers, Manufacturers, Importers and Distributors of Newly Deemed Products, located here for more information.
https://www.fda.gov/downloads/tobaccoproducts/guidancecomplianceregulatoryinformation/ucm501016.pdf
[4] https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM436468.pdf
[5] http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm
FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.
[6] http://www.fda.gov/ForIndustry/FDAeSubmitter

If you have any questions concerning this matter, please contact the Center for Tobacco Product's Office of Compliance and Enforcement via email at CTP-OCE-Postmarket@fda.hhs.gov.

Sincerely yours,

Ann Simoneau, J.D.
Director
Office of Compliance and Enforcement
Center for Tobacco Products