DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

December 22, 2017

NOT SUBSTANTIALLY EQUIVALENT

Toque Snuff Ltd.
Attn: Roderick Lawrie, Managing Director
Tiptoe Farmhouse, Tiptoe Farm
Cornhill on Tweed
Northumberland TD12 4XD, United Kingdom

FDA Submission Tracking Number (STN): SE0009635

Dear Mr. Lawrie:

We have completed our review of your Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce (SE Report), submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

New Tobacco Product

Tobacco Product Manufacturer:	Toque Snuff Ltd.
Tobacco Product Name[1]:	Toque Snuff Whiskey & Honey
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Loose Dry Snuff
Package Type:	Tin
Package Quantity:	10 grams
Characterizing Flavor:	Whiskey & Honey
Tobacco Cut Size:	Not Provided[2]

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] Applicant stated this is not applicable.

We have completed the review of your SE Report and have determined that it does not establish that the new tobacco product specified is substantially equivalent to the following predicate tobacco product:

Predicate Tobacco Product

Tobacco Product Manufacturer:	Wilsons & Co. (Sharrow) Ltd.
Tobacco Product Name[1]:	Wilsons Snuff
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Loose Dry Snuff
Package Type:	Tin
Package Quantity:	10 grams
Characterizing Flavor:	Whiskey and Honey Menthol
Tobacco Cut Size:	Not Provided[2]

We have described below our basis for this determination.

- Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: whisky and honey menthol) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: whisky and honey menthol) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

You have failed to provide sufficient information to support a finding of substantial equivalence; therefore, we are issuing an order finding that this new tobacco product is not substantially equivalent to an appropriate predicate tobacco product. Upon issuance of this order, your tobacco product is misbranded under section 903(a)(6) of the FD&C Act and adulterated under section 902(6)(A) of the FD&C Act. Failure to comply with the FD&C Act may result in FDA taking regulatory action without further notice. These actions may include, but are not limited to, civil money penalties, seizure, and/or injunction.

Additionally, FDA requests that within 15 days of this letter you submit a plan detailing the steps you plan to take to ensure that this misbranded and adulterated product is not further distributed, imported, sold, marketed, or promoted in the United States by others. Your plan should include information sufficient to distinguish this misbranded and adulterated product from legally marketed tobacco products, including, but not limited to lot numbers, manufacturing codes, and manufacturing dates. The plan should also include a list of your

direct accounts, and contain their contact information. Submit your plan to the address below with a cover letter that includes the following text in the subject line:

COMPLIANCE PLAN for SE0009635

FDA will post product identifying information on a list of tobacco products that are adulterated and misbranded due to an NSE order, available to the public at https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm371765.htm.

We remind you that you are required to update your listing information in June and December of each year under section 905(i)(3) of the FD&C Act. As part of this listing update, under section 905(i)(3)(B) of the FD&C Act, you must provide information on the date of discontinuance and product identity for any product you discontinue.

If you wish to request supervisory review of this decision under 21 CFR 10.75, please submit the request via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[3] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter), or mail to:

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

The CTP Portal and FDA Electronic Submission Gateway (ESG) are both generally available 24 hours a day, seven days a week. Submissions delivered to DCC by couriers or physical mail will be considered timely if received during delivery hours on or before the due date (see http://www.fda.gov/tobaccoproducts/aboutctp/contactus/default.htm); if the due date falls on a weekend or holiday the delivery must be received on the prior business day. We are unable to accept regulatory submissions by e-mail.

We request that your package be sent as a single submission with a cover letter that includes the following text in your subject line: **REQUEST FOR SUPERVISORY REVIEW for SE0009635**. In addition, we request that your package identify each basis for the request and contain all information on which you wish your request to be based; it may not contain any new data or analysis that was not part of your SE Report.

You may not legally market the new product described in this SE Report, unless it complies with the requirement in section 910(a)(2)(A) of the FD&C Act.

[3] The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

See the following website for additional information on these three pathways: http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/default.htm.

If you have any questions, please contact Moriya Caines, Regulatory Health Project Manager, at (301) 796 - 7676.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2017.12.22 08:12:58 -05'00'

Matthew Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products