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## QUESTION 1.

In your MRTP application you state “*Copenhagen® Fine Cut and variants thereof have been on the market since 1822. Since 2007, USSTC made minor modifications to Copenhagen® Snuff Fine Cut, which are the subject of a separate pending Substantial Equivalence review. The candidate product subject to the MRTPA is the product for which FDA granted grandfathered status (Grandfather Number – GF1200194) on November 1, 2012.*” You also state that “*The Copenhagen® Snuff fine cut used in the Oldham et al. (2014) study was obtained in 2012 and unlikely the specific formulation represented in the grandfathered product. HPHC data more specific to the candidate product are included in Section 7.1.*”

- You indicated that since 2007, USSTC made “minor modifications” to the candidate product. Did you report any data (tobacco blend, ingredients, HPHCs) in the MRTPA from any Copenhagen Fine Cut product that was the result of modifying the GF product? What are specific formulation differences between the product reported by Oldham (obtained in 2012) and the product that was granted GF status by the FDA on Nov 1, 2012?

## RESPONSE

In our MRTP application (MR0000108) we reported tobacco blend, ingredient, and HPHC data for the grandfathered product GF1200194. In addition, two sources in our application include certain data for modifications of the GF1200194 product:

1. In Appendix 7.4.4, we provide a list of historical analytical data reported to the Centers for Disease Control and Prevention (CDC). These CDC data are for reporting years 1997 to 2017.
  - For reporting years 1997 – 2007, the data are for the grandfathered version of Copenhagen® Snuff Fine Cut (GF1200194);
  - For reporting years 2008 – 2009, the data are for a modified version of GF1200194 that is not currently marketed;
  - For reporting years 2010 – 2017, the data are for a modified version of GF1200194 that is the subject of a pending Substantial Equivalence review (SE0000469 or “Provisional Product”) that is the currently-marketed version of Copenhagen® Snuff Fine Cut; and,
2. In the Oldham, *et al* study (See Table 7.5.4-1-1 in Section 7.5.4-1, Initial – Chemistry and Constituents – Literature Summary) data are reported for product obtained in 2012, the Provisional Product Copenhagen® Snuff Fine Cut SE0000469.

In general, the Provisional Product reported by Oldham, *et al.* differs from GF1200194 as follows:

-  (b) (4)
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Additionally, we provide [Table 1](#), [Table 2](#), and [Table 3](#) (See Appendix A), listing tobacco blends, ingredients, and the composition of Fermented Tobacco used as an inoculum, for GF1200194 and the Provisional Product (SE0000469).

## QUESTION 2.

Is the HPHC data included in Section 7.1 of the application from the grandfathered product (GF1200194) or from modified versions of this product?

## RESPONSE

The HPHC data included in Section 7.1 (Product Analysis – Harmful and Potentially Harmful Constituents [HPHC]) of the MRTPA MR0000108 is for the grandfathered product (GF1200194), not a modified version of GF1200194.

**APPENDIX A****Table 1: Tobacco Blends for GF1200194 and the Provisional Product (SE0000469)**

Component	Tobacco Type / Subcomponent	Unit of Measure	GF1200194 (Target)	Provisional Product (Target)
(b) (4)				

N/P - Not Present

**Table 2: Ingredients Added Directly to GF1200194 and the Provisional Product (SE0000469)**

Ingredient	Chemical Abstracts Service Number	Unit of Measure	GF1200194 (Target)	Provisional Product (Target)
(b) (4)				
Ammonium Carbonate <sup>1</sup>				(b) (4)
(b) (4)				

Ingredient	Chemical Abstracts Service Number	Unit of Measure	GF1200194 (Target)	Provisional Product (Target)
(b) (4)				
Ethyl Alcohol	(b) (4)			
(b) (4)				

Ingredient	Chemical Abstracts Service Number	Unit of Measure	GF1200194 (Target)	Provisional Product (Target)
(b) (4)				
Sodium Carbonate <sup>1</sup>				(b) (4)
				(b) (4)
Sodium Chloride				(b) (4)
				(b) (4)
Water <sup>2</sup>				(b) (4)
N/P - Not Present				
(b) (4)				

**Table 3: Composition of Fermented Tobacco for GF1200194 and the Provisional Product (SE0000469)**

<b>Component</b>	<b>GF1200194 (mg/g Fermented Tobacco) (Target)</b>	<b>Provisional Product (mg/g Fermented Tobacco) (Target)</b>
(b) (4)		
Ammonium Carbonate <sup>1</sup>		(b) (4)

Component	GF1200194 (mg/g Fermented Tobacco) (Target)	Provisional Product (mg/g Fermented Tobacco) (Target)
(b) (4)		
Ethyl Alcohol		(b) (4)
(b) (4)		

Component	GF1200194 (mg/g Fermented Tobacco) (Target)	Provisional Product (mg/g Fermented Tobacco) (Target)
		(b) (4)
Sodium Carbonate <sup>1</sup>		(b) (4)
		(b) (4)
Sodium Chloride		(b) (4)
		(b) (4)
Water <sup>2</sup>		(b) (4)
N/P - Not Present		(b) (4)