3.1.: DESCRIPTION OF TOBACCO PRODUCT (FORMULATION, MANUFACTURING, PACKAGING, STABILITY)

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3.1. DESCRIPTIVE INFORMATION

The candidate product is a grandfathered product (FDA Grandfather Status # GF1200194) (Appendix 2.3-1), commercially marketed in the U.S. as of February 15, 2007. As such, it is not a new tobacco product as defined by FDCA Section 910(a) (1) and does not require premarket review and authorization[1].

FDCA §911(d)(1) and (3) requires an MRTPA to include "a description of the proposed product" and "the formulation of the product." The Food and Drug Administration's (FDA's) Modified Risk Tobacco Product Application (MRTPA) Draft Guidance (2012) provides additional recommendations regarding an MRTPA's description of the product and its formulation.

As part of the formulation information that an applicant must submit under Section 911(d)(3), the Draft MRTPA Guidance recommends that applicants provide, among other information, "a description of manufacturing steps and quality control measures; how the design, and materials combine to produce the final product; performance criteria for the tobacco product; and shelf life data." These types of information do not pertain to a product's "formulation," but rather, relate to other subjects entirely. Section 911(d)(3) does not constitute proper authority for the Agency to expect submission of this information. Indeed, Congress did not authorize FDA to request or consider manufacturing processes as part of an MRTPA review. Only in Section 910, which governs FDA authorization of new tobacco products, did Congress include the additional mandate that FDA take into account manufacturing processes. Had Congress intended FDA to consider information about how an applicant manufactures a product when making an authorization determination for an MRTP claim, it would have explicitly included a requirement in Section 911 for such information, just as it did in Section 910. FDA also recommends information relating to the packaging of the product, but it is now well settled that packaging is not a part of the tobacco product. By providing manufacturing, packaging, shelf-life, and related information in this MRTPA, Altria Client Services LLC (ALCS) and United States Smokeless Tobacco Company LLC (USSTC) expressly reserve any legal objections regarding FDA's desire for such information when deciding whether to grant or deny authorization to market the candidate product with an MRTP claim.

In Section 3.1.1 we provide a complete listing of candidate product information including:

- brand name and subbrand name;
- product form, type, and flavor;
- design features (i.e., Product Requirements); and
- packaging type and size.

[1] 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.

In Section 3.1.2, we provide a narrative describing the candidate product formulation including:

- a description of tobacco used in the candidate product; and
- a complete list of other ingredients.

In Section 3.1.3, we provide a narrative describing the candidate product manufacturing process:

- tobacco receiving, processing, warehouse aging and quality control measures;
- manufacturing steps and quality control measures; and
- chemical analyses.

In Section 3.1.4, we provide a narrative describing the candidate product packaging materials.

In Section 3.1.5, we describe data establishing the candidate product stability through shelf life.

3.1.1. Description of the Candidate Product

3.1.1.1. Brand Name and Subbrand Name

The candidate product will be marketed with the following brand name and subbrand name: Copenhagen® Snuff Fine Cut

3.1.1.2. Form

The candidate product is a smokeless tobacco product in the form of loose, moist snuff. The form is depicted in the photograph below (Figure 3.1-1), which is an agriculturally-based loose, fine cut moist smokeless tobacco (MST) product placed in the mouth by adult tobacco consumers (ATCs).

Figure 3.1-1: MST Photograph

3.1.1.3. Heating Source

The product does not require a heating source for use.

3.1.1.4. Design Features

The candidate product is an agriculturally-based MST product. USSTC defines the final product design features as pH and percent oven volatiles (%OV), i.e., moisture content. Table 3.1-1 presents the target value and the upper and lower limits for each of the candidate product's design features.

Table 3.1-1: Design Features

Design Feature	Unit of Measure	Lower Limit	Target	Upper Limit
pH	N/A	(b) (4)		
Oven Volatiles (OV)	%			

N/A=not applicable

3.1.1.5. Quantitative Description of the Performance Criteria for the Candidate Product

After batch records are examined to verify that the candidate product has been manufactured according to the product requirements, it is released from manufacturing to commercial distribution. Verification includes conformance to the product design features (Table 3.1-1) pH and %OV.

3.1.1.6. Product Information

Table 3.1-2 lists additional candidate product information. The finished candidate product does not require special handling or storage upon commercial distribution.

Table 3.1-2: Product Information

Information Type	GF1200194 Product Information
Universal Product Code (UPC)	0-731071-9[1]
Brand / Sub-Brand	Copenhagen Snuff Fine Cut
Manufacturer	USSTC
Tobacco Product Category	Moist Snuff
Subcategory	Loose non-portioned
Tobacco Cut	Fine Cut
Package Type	Fiberboard Can/Metal Lid
Package Size	34.02 grams

Information Type	GF1200194 Product Information
Portion Weight	N/A
Portion Count	N/A
Portion Width	N/A
Portion Length	N/A
Portion Thickness	N/A
Tobacco Cut Size	(b) (4)
Identifying Flavor[2]	None

N/A – Not Applicable; the product is not portioned

[1] The UPC code is subject to change.

[2] CTP has not issued an explanation of what it considers to be a "characterizing flavor" or how it expects manufacturers to determine whether a particular smokeless tobacco product has a "characterizing flavor." Therefore, we use the term "Identifying Flavor" to indicate whether USSTC identifies the product by use of a flavor identifier, or whether USSTC does not use a flavor identifier to identify the product (i.e., None).

3.1.2. Formulation of the Candidate Product

This section details the candidate product formulation, which includes fermented tobacco and other ingredients.

3.1.2.1. Tobacco

All tobaccos used for production of the candidate product (Table 3.1-3) are grown in the U.S. Additionally, all the tobaccos used for making the candidate product are required by contract to be produced, harvested, cured, and prepared for sale in accordance with all applicable U.S. federal, state and local laws, rules, and regulatory requirements.

Products made from agricultural crops, including MST products, are subject to year-to-year natural variations that influence the quality and available quantity of the crop. To maintain the sensorial consistency of its MST products, USSTC makes adjustments to the tobacco subcomponent blends as needed.[2]

USSTC uses the following types of tobacco in the manufacture of the candidate product:

3.1.2.2. Dark Tobaccos

Dark Tobaccos (Figure 3.1-2) – Typically used in smokeless tobacco, dark tobacco types can be air-cured or fire-cured.

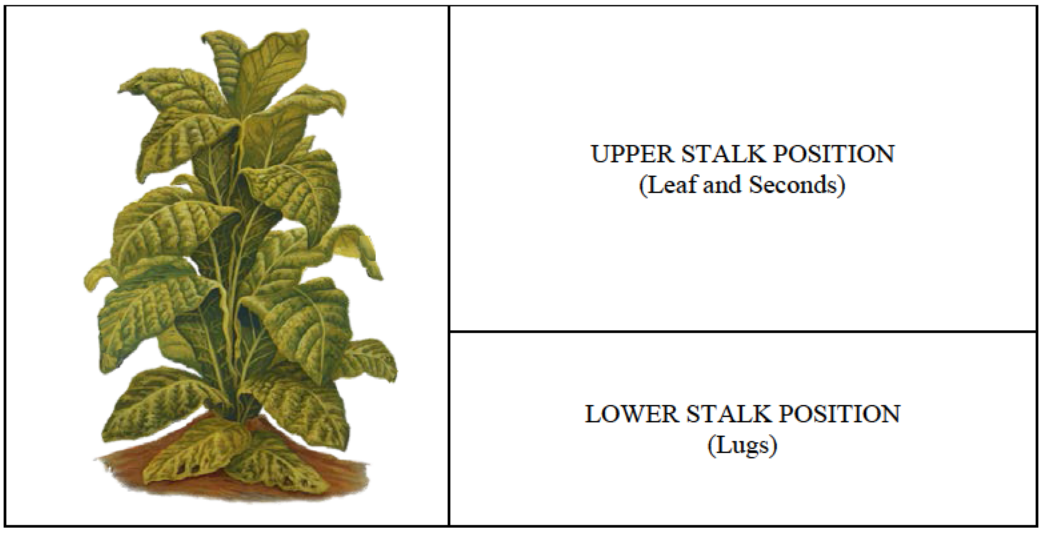
[2] Section III of CTP's Final Guidance, Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products (FDA, January 2011), which states: "At this time, FDA does not intend to enforce the requirements of sections 910 and 905(j) for tobacco blending changes required to address the natural variation of tobacco (e.g., blending changes due to variation in growing conditions) in order to maintain a consistent product."

Dark Air-Cured (DAC) – Tobacco that is cured on the stalk using ambient conditions (without the use of fire). Tobacco is hung in ventilated barns or field structures over a period of approximately 4 to 8 weeks. Natural temperature and humidity fluctuations assist in the curing of the tobacco during this period.

Dark Fire-Cured (DFC) – Tobacco that is cured on the stalk in low ventilation barns. Hardwood planks and saw dust are smoldered multiple times over an approximately 15 to 40 day period depending on weather conditions and manufacturing requirements. The tobacco is subjected to the resulting heat and smoke until cured to impart the hardwood smoke flavor onto the tobacco. Natural temperature and humidity fluctuations also assist in the curing of the tobacco during this period.

ALCS, on behalf of USSTC, uses a tobacco grading system for dark tobaccos (DAC and DFC) similar to industry standards established by the U.S. Department of Agriculture (USDA). Stalk position, color, and quality define the grade of tobacco. Stalk position refers to the relative position of the leaves on the stalk of the tobacco plant. Color and quality vary depending on type, growing conditions and curing conditions.

Figure 3.1-2: Dark Tobacco Plant (Used for Dark Fire-Cured and Dark Air-Cured Tobaccos)



Leaf and seconds are considered to be upper stalk. Upper stalk position typically refers to tobacco taken from the upper two-thirds portion of the stalk. These tobaccos have a heavy to medium body relative to the lugs. Approximately 87 percent by weight of the useable leaves from the plant come from the upper stalk positions.

Lugs are considered to be lower stalk. This position is located on the bottom third of the stalk. These leaves are thinner in body relative to the leaf/seconds. Approximately 13 percent by weight of the useable leaves from the plant come from the lower stalk position.

3.1.2.3. Burley Tobaccos

Burley Tobaccos (Figure 3.1-3) – Burley tobaccos are typically used in cigarette, smokeless tobacco and cigar products.

Burley tobacco is cured on the stalk using ambient conditions (without the use of fire). Tobacco is hung in ventilated barns or field structures over a period of approximately 4 to 8 weeks. Natural temperature and humidity fluctuations assist in the curing of the tobacco during this period.

Figure 3.1-3: Burley Tobacco Plant

ALCS uses a Burley tobacco grading system that is similar to industry standards established by the USDA. This system evaluates stalk position, color and quality. Stalk position refers to the relative position of the leaves on the stalk of the tobacco plant. Color and quality vary depending on type, growing conditions and curing conditions.

Leaf and seconds are considered to be upper stalk. Upper stalk position typically refers to tobacco taken from the middle-to-top portion of the stalk. These tobaccos have a heavy to medium body relative to the lugs. Approximately 60 percent by weight of the useable leaves from the plant come from the upper stalk position.

Lugs are considered to be lower stalk. This stalk position begins just below the middle of the stalk and goes to the bottom of the stalk. These leaves are thinner in body relative to the leaf. Approximately 40 percent by weight of the useable leaves from the plant come from the lower stalk position.

Table 3.1-3 shows the tobacco composition used in the candidate product. The target value and the upper and lower limits are listed for each tobacco type or subcomponent. The candidate product is in a loose format, with the tobacco cut described as fine cut. The tobacco is cu (b) (4) at (b) (4) cuts per inch (CPI), and subsequently screened through (b) (4) (b) (4) to achieve the desired strand length.

Table 3.1-3: Tobacco Composition

Component	Tobacco Type / Subcomponent	Unit of Measure	Lower Limit	Target	Upper Limit
Tobacco	(b) (4)	mg/gram	(b) (4)		
Tobacco	(b) (4)	mg/gram			
Tobacco	(b) (4)	mg/gram			
Tobacco	(b) (4)	mg/gram			

(b)

3.1.2.4. Other Ingredients

Table 3.1-4 lists each product ingredient, other than tobacco, and its function and use level. The ingredient column reflects the "common" name, if appropriate, and the table specifies the target value, if any, and the upper and lower limits for each ingredient. Some ingredients do not have target values listed, because there is no target value. Specifically, amounts of sodium carbonate, ammonium carbonate, and water (b) (4) in Table 3.1-1 and in Section 3.1.3.3.7.

ALCS, on behalf of USSTC assesses the toxicological impact of ingredients and their use levels as part of the evaluation conducted according to the "Product Integrity Review and Toxicological Evaluation Guideline, Smokeless Tobacco Products: Test Articles, Prototypes, and Products" (Appendix 3.1-1) and the "Product Integrity Toxicological Evaluation Framework Overview" (Appendix 3.1-2).

Table 3.1-4: Non-Tobacco Ingredients Used

Ingredient	Chemical Abstracts Service Number	Function	Unit of Measure	Lower Limit	Target	Upper Limit
(b) (4)						
Ammonium Carbonate						(b) (4)
						(b) (4)

Ingredient	Chemical Abstracts Service Number	Function	Unit of Measure	Lower Limit	Target	Upper Limit
						(b) (4)
Ethyl Alcohol						(b) (4)
						(b) (4)

Ingredient	Chemical Abstracts Service Number	Function	Unit of Measure	Lower Limit	Target	Upper Limit
						(b) (4)
Sodium Carbonate						(b) (4)
Sodium Chloride						(b) (4)
						(b) (4)
Water						(b) (4)

N/A – Not Applicable

[1] (b) (4) f ammonium carbonate and sodium carbonate.

b

[2] USSTC does not control to target amounts of water. Rather, USSTC controls to the targeted design feature of % OV.

Table 3.1-5 lists the indirect additives associated with the fiberboard can and metal lid that are used for the packaging of the candidate product.

Table 3.1-5: Indirect Additives Associated with the Fiberboard Can and Metal Lid

Ingredient	Chemical Abstracts Service Number	Function
(b) (4)		

N/A=not applicable

3.1.3. Candidate Product Manufacturing Process

USSTC and its predecessors have been manufacturing this product since 1822. The earliest documented description of the manufacturing process is dated 1905, preceding analytical instrumentation and specific analytical details which have become available only in the recent decades. The current manufacturing process is fundamentally unchanged from the historical process which includes the use of tobacco, water, salts, and flavors (Section 2.3.3.1). Over the years USSTC optimized the manufacturing process for efficiency with larger batch sizes, equipment automation, and quality control measures incorporated to ensure product consistency. Over time, the manufacturing process has been optimized to achieve a high quality product and a consistent sensorial experience. Additionally, USSTC implemented sanitation practices to inhibit tobacco-specific nitrosamines (TSNA) formation during fermentation and subsequent shelf storage (Fisher et al., 2012).

USSTC employs contamination control and sanitation procedures throughout the manufacturing process to ensure product quality. These procedures apply to all operations and personnel involved in the production, shipping, and storage of product at USSTC facilities. USSTC further achieves product quality through establishment and implementation of quality control measures. Section 3.1.3.1 details the quality system governing the manufacturing and packaging of the candidate product.

(b) (4)

Upon completion of the Fermentation process, the tobacco proceeds to the Finishing process which adds additional salts, flavors, and water. USSTC then packages the finished product into cans. Section 3.1.3.3 details each of the above-referenced manufacturing processes.

3.1.3.1. Quality Requirements

The Altria Quality Requirements Manual (AQRM) defines the quality requirements for the tobacco products manufactured and marketed by Altria Operating Companies. The AQRM provides the framework for USSTC's Quality Management System, including the methods used in, and the facilities and controls used for the manufacture, packaging, and storage of USSTC products. USSTC is accountable for ensuring documented processes (e.g., procedures) are in place, where applicable, that conform to the Altria Quality Requirements and that clearly describe performance to support product quality.

The AQRM prescribes quality requirements that include the following:

- personnel training, skills, and experience;
- contamination control of facilities, equipment, and product;
- inspection, measuring, and test equipment management;
- laboratory controls, including test methods and validations, sampling, and test result management;
- records, data, and documentation management and practices;
- supplier and material qualification and management;
- identification and traceability practices for materials, components, product, and equipment;
- manufacture and process controls, including product requirements and specifications;
- acceptance activities for incoming, in-process, and finished product;
- escalating issues, and investigating and trending product quality incidents (PQIs) and product quality complaints;
- product recall;
- product labeling and packaging;
- handling, storage and distribution;

- continual improvement including corrective and preventive action (CAPA) management and quality audits; and
- management and oversight of testing laboratories.

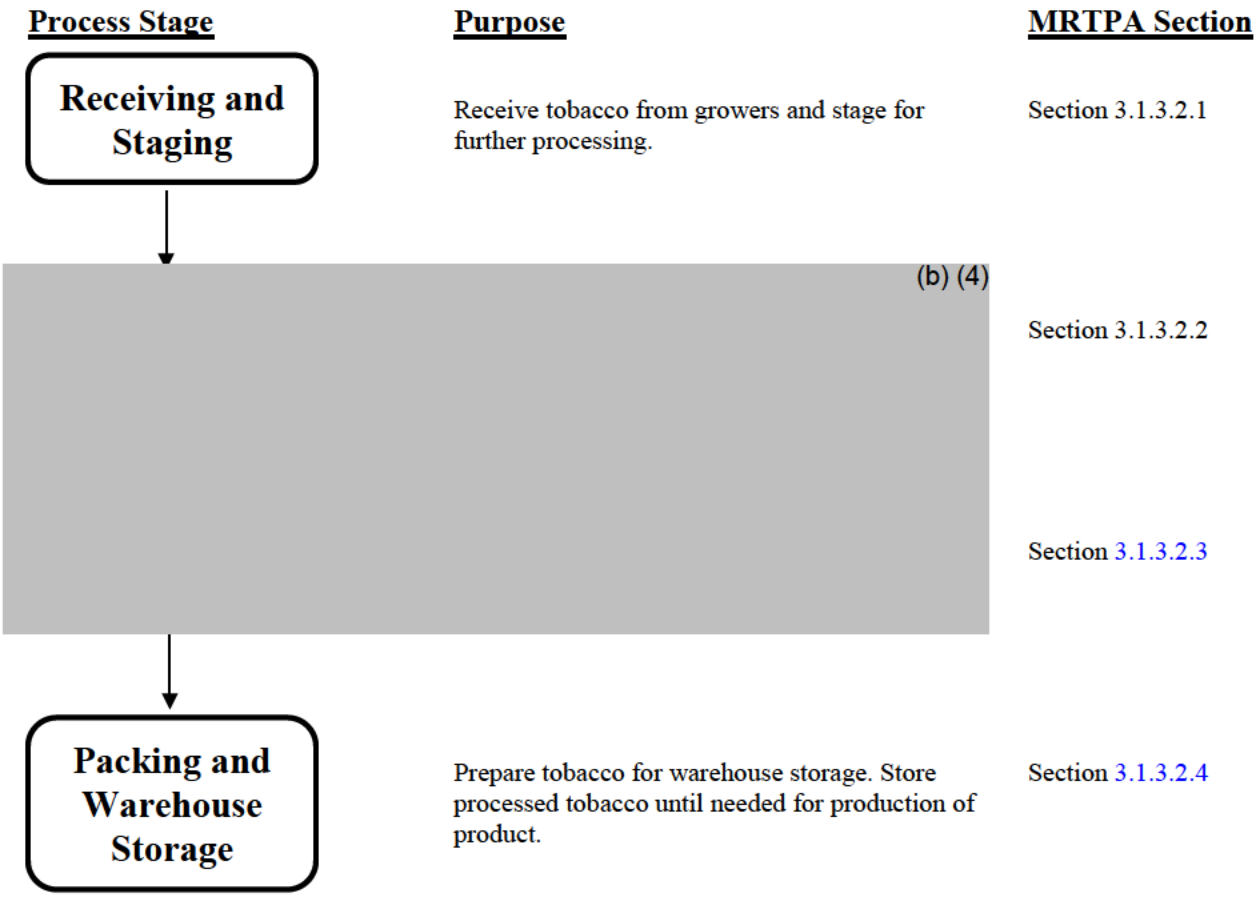
USSTC characterizes these quality activities as Process Controls, Product Requirements, or Batch Acceptance:

- Process Control measurements help minimize variation and meet product requirements.
- Product Requirements ensure manufacturing, packaging, and labeling of finished product as intended, including conformance to applicable regulatory requirements. Product Requirements also dictate conformance to raw material, component, intermediate material, in-process requirement, and finished product attributes. Standard Operating Procedures and Work Instructions direct activities. Deviation from a Product Requirement, such as nonconformance to a Bill of Material (BOM) or discovery of a non-product related material (NPRM), is a product quality incident (PQI). USSTC investigates and documents PQIs, including evaluation, identification, segregation, and disposition. ALCS tracks and systematically monitors PQI investigations in order to conduct periodic trend analysis and identify where CAPA may be needed.
- Batch Acceptance activities document conformance to Product Requirements and define the conditions or characteristics of a process or product that must be fulfilled before the product can be released to the next process step or released for distribution. These include execution of USSTC's Quality Management System such as inspections, verifications and checks of the quality requirements (e.g., sanitation, start-up/changeover, test equipment, etc.).

3.1.3.2. Leaf Processing Steps and Quality Control Measures

The manufacturing process for the candidate product begins with receipt of tobacco from growers. A series of steps prepare the tobacco for use in the product. Figure 3.1-4 shows a general overview of Leaf Processing. The following subsections discuss the relevant quality control activities at each process step. The facility Process Control Plan provides the specific requirements of the process (i.e., Process Controls, Product Requirements and Batch Acceptance Requirements) for the candidate product.

Figure 3.1-4: General Process Overview of Leaf Processing



3.1.3.2.1. Leaf Processing – Receiving and Staging

Growers deliver tobacco to USSTC's primary processing facility or receiving stations. USSTC visually inspects tobacco for NPRMs and verifies leaf quality, including grading accuracy and moisture. Additionally, we randomly sample tobacco deliveries and test for crop protection agent (CPA) levels per internal requirements. Since there are no federal limits established for CPAs that apply to domestically grown tobacco, USSTC voluntarily utilizes the USDA Expanded List Maximum Allowable Levels (MALs) and CORESTA Guidance Residue Levels (GRLs) (Appendix 3.1-3 and Appendix 3.1-4). USSTC holds sampled tobacco pending review of test results and discards tobacco exceeding these CPA levels in accordance with USSTC's disposition process. Following receipt, tobacco is weighed, tagged for traceability, and staged for the next process step.

3.1.3.2.2. Leaf Processing – (b) (4)

(b) (4)

(b) (4)

3.1.3.2.3. Leaf Processing – (b) (4)

(b) (4)

Table 3.1-6: Tobacco Moisture Ranges

Component	Subcomponent	Unit of Measure	Lower Limit	Target	Upper Limit
Tobacco	(b) (4)	%OV	(b) (4)		
Tobacco		%OV			
Tobacco		%OV			

3.1.3.2.4. Leaf Processing – Packing and Warehouse Storage

At this stage, USSTC packs the tobacco by type and grade into containers and transports it to warehouses for storage and aging. The warehouse stores DAC and Burley tobaccos typically for a minimum of (b) (4) and DFC tobaccos typically for a minimum of (b) (4) prior to use in manufacturing the finished product. (b) (4)

3.1.3.3. Candidate Product Manufacturing Steps and Quality Control Measures

Figure 3.1-5 depicts a general overview of the process for manufacturing the candidate product. We discuss the relevant quality control activities for each process step in the following subsections. USSTC manufactures the candidate product in a batch process using the process steps shown and the listed quality control activities at each step. The facility Process Control Plan provides the specific requirements of the process (i.e., Process Controls, Product Requirements and Batch Acceptance Requirements) for the candidate product.

Figure 3.1-5: General Process Overview of Candidate Product Manufacturing

Process Stage	Purpose	MRTPA Section
(b) (4)		Section 3.1.3.3.1
		Section 3.1.3.3.2
		Section 3.1.3.3.3
		Section 3.1.3.3.4
		Section 3.1.3.3.5
		Section 3.1.3.3.6
		Section 3.1.3.3.7
		Section 3.1.3.3.8

Process Stage	Purpose	MRTPA Section
(b) (4)		Section 3.1.3.3.9

3.1.3.3.1. Candidate Product Manufacturing – (b) (4)

(b) (4)

Table 3.1-7: Tobacco Leaf Blend Types and Subcomponents

Tobacco[1]
(b) (4)

[1] Numbers may not sum to 100 due to rounding.

Table 3.1-8: Tobacco Leaf Blend Types and Subcomponents by Stalk Position

Tobacco Unique Identifiers	Unit of Measure	Candidate Product
(b) (4)		

Tobacco Unique Identifiers	Unit of Measure	Candidate Product
		(b) (4)

3.1.3.3.2. Candidate Product Manufacturing – (b) (4)

(b) (4)

Table 3.1-9: (b) (4) Formulation

Ingredient	CAS#	Unit of Measure	Target
			(b) (4)

(b)

(b) (4)

3.1.3.3.3. Candidate Product Manufacturing – (b) (4)

(b) (4)

Table 3.1-10.

Table 3.1-10: Candidate Product (b) (4)

Cuts / Inch	Double / Single Cut	Blade
(b) (4)		

3.1.3.3.4. Candidate Product Manufacturing – (b) (4)

(b) (4) in Table 3.1-11.

Table 3.1-11: Dry Flour Moisture Ranges

Component	Unit of Measure	Lower Limit	Target	Upper Limit
Tobacco	%OV	(b) (4)		

(b) (4)

The tobacco at this stage is referred to as dry flour

3.1.3.3.5. Candidate Product Manufacturing – (b) (4)

(b) (4)

(b) (4) in Section 3.1.3.3.6.

(b) (4)

(b) (4)

Table 3.1-12: (b) (4)

(b) (4)

(b) (4)

Table 3.1-13: Into-Cure Formulation

Ingredient	%OV	Weight (Lbs.)
(b) (4)		

(b

3.1.3.3.6. Candidate Product Manufacturing – (b) (4)

(b) (4)

Table 3.1-14: (b) (4)

Parameter	Unit of Measure	Target	Test Interval
(b) (4)			

Table 3.1-15: (b) (4)

Component	(b) (4)
(b) (4)	

Component	(b) (4)

(b) (4)

(b) (4)

Table 3.1-16: (b) (4)

(b) (4)

Table 3.1-17: (b) (4)

(b) (4)

(b) (4)

Table 3.1-18: (b) (4)

Parameter	Low Alarm	Target	High Alarm
(b) (4)			

(b) (4)

3.1.3.3.7. Candidate Product Manufacturing – (b) (4)

(b) (4)

(b) (4)
(Table 3.1-1).

Table 3.1-19: Finishing Formulation

Ingredient	% OV	Weight (Lbs.)
Tobacco (OOC)	(b) (4)	
Water[1]		
Sodium Carbonate[1]		
Ammonium Carbonate[1]		
Sodium Chloride		
Flavor		
Total		

(b) (4) Table 3.1-1.

3.1.3.3.8. Candidate Product Manufacturing – (b) (4)

(b) (4)

3.1.3.3.9. Candidate Product Manufacturing – (b) (4)

Following the packing process, shipper cases are held (b) (4)

(b) (4)

3.1.3.4. Chemical Analyses

3.1.3.4.1. Analytical Test Method Documentation

USSTC uses a variety of analytical test methods to determine conformance to product requirements and final product batch acceptance. These methods are documented according to FDA's Guidance for Industry – Analytical Procedures and Methods Validation for Drugs and Biologics, July 2015.

The standard test methods (ST-TM) used to analyze the candidate product are described below.

Table 3.1-20: Determination of (b) (4) Components by Near-Infrared

ST-TM-235-104 Determination of (b) (4) Components by Near-Infrared (Appendix 3.1-5)
This method quantitates ions in solution using near-infrared analysis coupled with chemometric algorithms. These results are used to verify the concentration of ingredients used during (b) (4) make-up. Revision History - Appendix 3.1-6

Table 3.1-21: Rapid Determination of pH in Smokeless Tobacco

ST-TM-410-314 Rapid Determination of pH in Smokeless Tobacco (Appendix 3.1-7)
This method describes the measurement procedure for pH analysis for all processed tobacco types. Tobacco in deionized water is stirred for 5-10 minutes dependent on sample type before pH electrode measurement. Revision History - Appendix 3.1-8

Table 3.1-22: Determination of pH in Smokeless Tobacco

ST-TM-410-334 Determination of pH in Smokeless Tobacco (Appendix 3.1-9)
This method describes the measurement procedure for pH analysis for all processed tobacco types. Tobacco in deionized water is stirred for no less than 60 minutes before pH electrode measurement. Revision History - Appendix 3.1-10

Table 3.1-23: Determination of Flavors in Smokeless Tobacco by GC-MS

ST-TM-410-634 Determination of Flavors in Smokeless Tobacco by GC-MS (Appendix 3.1-11)
This method describes the procedure for extracting and analyzing finished goods samples for flavor. It confirms that the correct flavors were added during manufacturing by comparing chromatographic profiles of the sample and historical data. Revision History - Appendix 3.1-12

Table 3.1-24: Determination of Volatiles in Smokeless Tobacco by Mechanical Convection Oven

ST-TM-440-254 Determination of Volatiles in Smokeless Tobacco by Mechanical Convection Oven (Appendix 3.1-13)
This method describes the procedure for determining of the weight-percent oven volatiles (%OV) of tobacco products using a mechanical convection oven. Oven volatiles are those compounds in tobacco that are evolved by treatment in a mechanical convection oven at 100 degrees Celsius for 3 hours. Revision History - Appendix 3.1-14

Table 3.1-25: Determination of Oven Volatiles in Smokeless Tobacco Products by Microwave Moisture Analyzer

ST-TM-440-264 Determination of Oven Volatiles in Smokeless Tobacco Products by Microwave Moisture Analyzer (Appendix 3.1-15)
This method describes the procedure for rapid microwave volatiles determination of smokeless tobacco using the CEM SMART™ System Microwave Moisture/Solids Analyzer. Results are reported as %OV. Revision History - Appendix 3.1-16

Table 3.1-26: (b) (4)

(b) (4) **(Appendix 3.1-17)**
(b) (4) ppendix 3.1-18

3.1.4. Packaging Materials

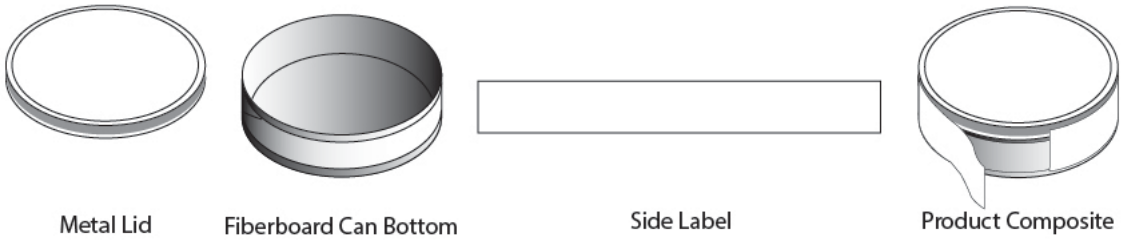
Table 3.1-27 lists the package material assemblies. The packaging assemblies are further depicted in Figure 3.1-5.

Table 3.1-27: Package Material Assembly

Material	Package Material Description
Lid	Metal
Can Bottom	Fiber Board
Side Label	Paper

Each of the packaging materials that are in direct contact with the candidate product conforms to the standard for indirect food additives set forth in FDA's Title 21 of the Code of Federal Regulations (CFR), as more fully discussed in the following sections.

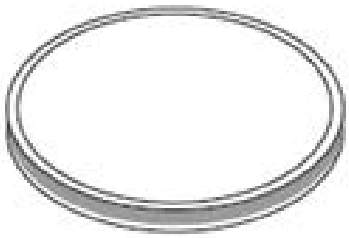
Figure 3.1-6: Detail of the Packaging



3.1.4.1. Lids

The metal lid, depicted in Figure 3.1-7 is comprised of tin plated steel and is punch pressed to make the lid configuration. The inside of the lid has an enamel coating to prevent premature oxidation of the tin plate coating. The tin plate coating conforms to 21 CFR § 174.5, and the enamel coating conforms to 21 CFR § 175.300.

Figure 3.1-7: Diagram of Metal Lid



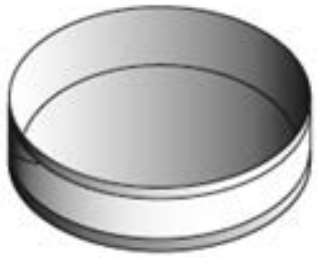
3.1.4.2. Can

The can bottom, depicted in Figure 3.1-8 is made of recycled fiber board materials with a wax coating inside. The recycled fiber board conforms to 21 CFR § 176.170, 21 CFR § 176.180 and 21 CFR § 176.260. The wax coating conforms to 21 CFR § 176.170 and 21 CFR § 176.180.

The fiber board can bottom is currently imprinted with a sell-by date of (b) weeks from the date of finishing, as determined by the internal and/or external ATC taste panel and analytical shelf life evaluation described in Section 3.1.5 and Section 7.2. USSTC also

imprints the can bottom with a traceability code and a toll free telephone number for adult consumer comments.

Figure 3.1-8: Diagram of Fiber Board Can Bottom



3.1.4.3. Side Label

The product uses a Coated One Side (C1S) paper label, as shown in Figure 3.1-9.

Figure 3.1-9: Diagram of Side Label

3.1.4.4. Adhesive

The hot melt adhesive used to attach the side label to the finished can (lid and can bottom) conforms to 21 CFR § 175.105. The hot melt adhesive is a mixture of wax (viscosity modifiers), resin (tackifier), and the base polymer (backbone to provide strength).

3.1.5. Data Establishing the Stability of the Candidate Product through Shelf Life

The shelf life of the candidate product is 6 weeks from the date of finishing, which was established through sensorial assessment of the candidate product well before the FSPTCA's grandfathered date of Feb. 15, 2007. Supporting data, including product chemistry and microbiology, demonstrate the stability of the candidate product over its shelf life. The following sections describe these data. Additional product chemistry measures indicative of product sensorial acceptability, including flavor loss and volatilization of certain salts and aromas, are not analytically measured. Rather, these changes are assessed sensorially.

3.1.5.1. Candidate Product Shelf Life – Sensory

After manufacturing, a smokeless tobacco product begins to undergo changes such as moisture loss, flavor loss, and volatilization of certain salts and aromas. Over time, these

changes alter the perceptible taste, aroma, visual, and textural characteristics of the product until such time that the ATC perceives that the product no longer has the expected sensory experience. ATCs recognize product that is lighter in color, less moist, having less robust flavor and aroma as having a less than acceptable sensory experience. USSTC defines the end of shelf life as the point at which the ATC considers the cumulative effect of these characteristics to provide less than the expected sensory experience. Internal and/or external ATC taste panels assess sensorial acceptability, including changes in taste, aroma, visual, and textural characteristics of a smokeless tobacco product. ALCS conducted further sensorial assessments of the candidate product with ATC taste panels in 2017 (Appendix 3.1-19).

3.1.5.2. Candidate Product Shelf Life – Chemistry

The analytical stability data for the candidate product are presented in Section 7.2.

3.1.5.3. Candidate Product Shelf Life – Microbiology

In addition to sensory and product chemistry evaluation discussed in the preceding sections, we present a series of microbiological evaluations of the candidate product in the following sections, which demonstrate the expected microbiological stability of the candidate product through its shelf life.

3.1.5.3.1. Total Aerobic Microbial Counts (TAMC) and Total Yeast and Mold Counts (TYMC)

TAMC and TYMC studies have been conducted to determine the microbial stability of the candidate product following the manufacturing process and during retail storage. The results of these analyses, included in Appendix 3.1-20 ("Copenhagen® Snuff Fine Cut Total Aerobic Microbial Count and Total Yeast and Mold Count", dated September 27, 2017), demonstrate the candidate product is stable throughout shelf life and does not support proliferation of yeasts and molds.

3.1.5.3.2. Microbial Challenge Study

Challenge studies are conducted to determine the potential for pathogenic microbiological growth following the manufacturing process. The results of the challenge study for the product, included in Appendix 3.1-21 ("Report on Copenhagen® Snuff Fine Cut", dated August 22, 2017), demonstrate the candidate product is not conducive to survival of the pathogens *Listeria monocytogenes*, *Salmonella spp.*, and of *Escherichia coli O157: H7*.

3.1.5.4. Candidate Product Stability Summary

Based on the ATC taste panel results, analytical stability data presented in Section 7.2, and the microbiological stability data, USSTC concludes that the candidate product is stable over its shelf life.

3.1.6. Literature Cited

Fisher, M. T., Bennett, C. B., Hayes, A., Kargalioglu, Y., Knox, B. L., Xu, D., . . . Gaworski, C. L. (2012). Sources of and technical approaches for the abatement of tobacco specific nitrosamine formation in moist smokeless tobacco products. *Food and chemical toxicology, 50*(3-4), 942-948.