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Given the above, all interested persons should refer to the Federal Food, Drug, and Cosmetic Act, and its implementing regulations, as well as guidance documents and webinars prepared by FDA, for information on FDA's tobacco authorities and regulatory framework. This document does not bind FDA in its review of any tobacco product application and thus, you should not use this document as a tool, guide, or manual for the preparation of applications or submissions to FDA.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
Silver Spring, MD 20993

MEMORANDUM

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Subject: Unique Identification of Tobacco Products

This memorandum identifies the properties that are needed to uniquely identify a tobacco product. This memorandum supersedes three previous memos, dated October 20, 2014, June 2, 2015¹, and October 6, 2016, that addressed unique identification for three categories of tobacco products: cigarettes, smokeless tobacco products, and roll-your-own tobacco products. This new memorandum corrects a few errors in the October 6, 2016, memorandum. It addresses eight categories² of tobacco products, listing properties inherent to each category and subcategory. In addition, additional properties necessary to uniquely identify a single product are listed within the category/subcategory. As FDA has not previously used many of these properties to identify tobacco products, this document includes definitions of many properties in Appendix 3.

When receiving marketing applications for tobacco products, FDA needs to identify the individual product that is the subject of each application. The pieces of information that uniquely identify a tobacco product are referred to as properties. For example, the product name (i.e., brand and subbrand) is a property that helps identify each tobacco product. However, product name alone is not sufficient to uniquely identify each tobacco product. In order to determine properties needed to uniquely identify each tobacco product, it is

¹ See Appendix 1 for June 2, 2015, memo.

² This includes categories for all tobacco products listed in the proposed deeming rule.

Unique Identification of Tobacco Products

necessary to determine the applicability of different properties, as each type of product has different properties. For example, one property of combusted cigarettes is length, whereas this property is not applicable to loose moist snuff.

What is often called product type is equivalent to the combination of product category and subcategory. As an illustration, the product type often referred to as “loose moist snuff” falls under the category “smokeless tobacco product” and subcategory “loose moist snuff.” Each product category has multiple subcategories. For example, some of the subcategories within the smokeless tobacco product category are loose moist snuff, portioned moist snuff, and portioned snus. Each category has a distinct set of properties that distinguish that category from any other category. Similarly, within each category, the subcategories have a distinct set of properties which distinguish one subcategory from another. Therefore, by knowing the product type of a given tobacco product, FDA inherently knows some of the properties associated with that product. However, additional identifying properties are needed in order to distinguish an individual product within a given category/subcategory from other products within that category/subcategory; determination of what identifying properties are necessary depends in part on the range of products that a manufacturer has.

It should be noted that the properties needed to uniquely identify tobacco products is determined by FDA based on experience reviewing regulatory submissions for these products. FDA has significant experience with cigarettes, smokeless tobacco products, and roll-your-own tobacco products, and the properties in this memo are based on this experience. FDA only recently began regulating the other categories of products identified in this memo and has received a limited number of regulatory submissions for these types of products. Therefore, more properties for these types of products will likely be identified by FDA as more experience is gained.

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CIGARETTES

Category properties:

Consumption:	Puffed and/or inhaled
Assembly:	No user assembly required
Tobacco filler:	Solid (cut tobacco leaf)
Extent of heating:	Combusted or non-combusted
Tobacco wrapper:	Cellulose-based paper ³ or material other than paper or tobacco leaf

Combusted, Filtered

Subcategory properties:

Extent of heating:	Combusted
Tobacco wrapper:	Cellulose-based paper ³
Filtration:	Contains a filter

Product properties:

Package type:	Hard pack, soft pack, clam shell, etc.
Package quantity:	20 cigarettes, 25 cigarettes, etc.
Length:	89 mm, 100 mm, etc.
Diameter:	6 mm, 8.1 mm, etc.
Ventilation:	None ⁴ , 10%, 25%, etc.
Characterizing flavor:	None, menthol
Additional properties ⁵ :	Green, premium, red, FSC, etc.

³ Cellulose-based paper does not contain tobacco.

⁴ "None" is also considered 0%.

⁵ Additional properties will be added when the listed properties are not sufficient to identify a tobacco product; additional properties necessary for product identification may not be identified during acceptance phase, but may be found during scientific review.

Combusted, Non-filtered

Subcategory properties:

Extent of heating:	Combusted
Tobacco wrapper:	Cellulose-based paper ³
Filtration:	Does not contain a filter

Product properties:

Package type:	Hard pack, soft pack, clam shell, etc.
Package quantity:	20 cigarettes, 25 cigarettes, etc.
Length:	89 mm, 100 mm, etc.
Diameter:	6 mm, 8.1 mm, etc.
Characterizing flavor:	None, menthol
Additional properties ⁵ :	Green, premium, red, FSC, etc.

Combusted, Other

Subcategory properties:

Extent of heating:	Combusted
Tobacco wrapper:	Material other than paper or other than tobacco leaf
Filtration:	Generally does not contain a filter

Product properties:

Package type:	Hard pack, soft pack, clam shell, etc.
Package quantity:	20 cigarettes, 25 cigarettes, etc.
Length:	89 mm, 100 mm, etc.
Diameter:	6 mm, 8.1 mm, etc.
Ventilation:	None ⁴ , 10%, 25%, etc.
Characterizing flavor:	None, menthol
Additional properties ⁵ :	Green, premium, red, FSC, wrapper material (e.g, tendu leaf, corn husk, banana leaf), machine-made, hand-rolled, etc.

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Non-Combusted

Subcategory properties:

Extent of heating:	Heated but not combusted
Tobacco wrapper:	Cellulose-based paper ³ or material other than paper or tobacco leaf
Filtration:	Does or does not contain a filter

Product properties:

Package type:	Hard pack, soft pack, clam shell, etc.
Package quantity:	20 cigarettes, 25 cigarettes, etc.
Length:	89 mm, 100 mm, etc.
Diameter:	6 mm, 8.1 mm, etc.
Ventilation:	None ⁴ , 10%, 25%, etc.
Characterizing flavor:	None, menthol, etc.
Source of energy:	Charcoal, electrical heater, etc.
Additional properties ⁵ :	Green, premium, red, FSC, etc.

ROLL-YOUR-OWN TOBACCO PRODUCTS

Category properties:

Consumption:	Puffed and/or inhaled
Extent of heating:	Combusted or not applicable
Assembly:	User assembly of multiple roll-your-own tobacco products
Tobacco filler:	None or solid (cut tobacco leaf)

Roll-Your-Own Tobacco Filler

Subcategory properties:

Extent of heating:	Combusted
Tobacco wrapper:	None
Assembly:	User assembly with rolling paper or cigarette tube
Tobacco filler:	Solid (cut tobacco leaf)
Filtration:	Does not include a filter

Product properties:

Package type:	Bag, pouch, etc.
Package quantity:	20 grams, 16 ounces, etc.
Characterizing flavor:	None, menthol
Additional properties ⁵ :	Green, premium, Virginia blend, etc.

Rolling Paper

Subcategory properties:

Extent of heating:	Not applicable
Tobacco wrapper:	Cellulose-based paper ³
Assembly:	User assembly with roll-your-own tobacco filler
Tobacco filler:	None
Filtration:	Does not include a filter

Product properties:

Package type:	Box, booklet, etc.
Package quantity:	50 sheets, 200 papers, etc.
Length:	79 mm, 100 mm, 110 mm, etc.
Width:	28 mm, 33 mm, 45 mm, etc.
Characterizing flavor:	None, menthol, tobacco ⁶
Additional properties ⁵ :	Green, lightweight, cut corners, premium, wrapper material (e.g., wood, hemp, flax), etc.

⁶ Tobacco is a characterizing flavor when tobacco flavoring is added to components that do not contain tobacco.

Filtered Cigarette Tube

Subcategory properties:

Extent of heating:	Not applicable
Tobacco wrapper:	Cellulose-based paper ³
Assembly:	User assembly with roll-your-own tobacco filler
Tobacco filler:	None
Filtration:	Includes a filter

Product properties:

Package type:	Bag, box, etc.
Package quantity:	100 tubes, 200 tubes, etc.
Length:	89 mm, 100 mm, etc.
Diameter:	6 mm, 8.1 mm, etc.
Ventilation:	None ⁴ , 10%, 25%, etc.
Characterizing flavor:	None, menthol, tobacco ⁶
Additional properties ⁵ :	Green, charcoal, premium, etc.

Non-Filtered Cigarette Tube

Subcategory properties:

Extent of heating:	Not applicable
Tobacco wrapper:	Cellulose-based paper ³
Assembly:	User assembly with roll-your-own tobacco filler
Tobacco filler:	None
Filtration:	Does not include a filter

Product properties:

Package type:	Bag, box, etc.
Package quantity:	100 tubes, 200 tubes, etc.
Length:	89 mm, 100 mm, etc.
Diameter:	6 mm, 8.1 mm, etc.
Characterizing flavor:	None, tobacco ⁶ , menthol
Additional properties ⁵ :	Green, lightweight, premium, etc.

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Filter

Subcategory properties:

Extent of heating:	Not applicable
Tobacco wrapper:	Cellulose-based paper ³
Assembly:	User assembly with other roll-your-own tobacco products
Filtration:	Includes a filter
Tobacco filler:	None

Product properties:

Package type:	Bag, box, etc.
Package quantity:	100 filters, 200 filters, etc.
Length:	8 mm, 12 mm, etc.
Diameter:	6 mm, 8.1 mm, etc.
Ventilation:	None ⁴ , 10%, 25%, etc.
Characterizing flavor:	None, menthol, tobacco ⁶
Additional properties ⁵ :	Green, charcoal, premium, etc.

Paper Tip

Subcategory properties:

Extent of heating:	Not applicable
Tobacco wrapper:	Cellulose-based paper ³
Assembly:	User assembly with other roll-your-own tobacco products
Filtration:	Does not include a filter
Tobacco filler:	None

Product properties:

Package type:	Bag, box, etc.
Package quantity:	200 tips, 275 tips, etc.
Characterizing flavor:	None, tobacco, etc.
Length:	12 mm, 15 mm, etc.
Width:	27 mm, etc.
Additional properties ⁵ :	Unbleached, pre-curved, etc.

Roll-Your-Own Co-Package

Subcategory properties:

Extent of heating:	Combusted or not applicable
Tobacco wrapper:	Cellulose-based paper ³
Assembly:	User assembly with components contained in product
Tobacco Filler:	None or solid (cut tobacco leaf)
Filtration:	Includes a filter or does not include a filter

Product properties⁷:

Components ⁸ :	Any combination of roll-your-own tobacco filler, rolling paper, filtered cigarette tube, filter, non-filtered tube, and/or paper tip
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Other

Subcategory properties:

Extent of heating:	Combusted or not applicable
Tobacco wrapper:	Cellulose-based paper ³ or material other than paper or tobacco
Assembly:	User assembly with other roll-your-own tobacco products
Filtration:	Includes a filter, does not include a filter
Tobacco filler:	None or solid (cut tobacco leaf)

Product properties⁹:

Package type:	Box, bag, booklet, etc.
Package quantity:	200 tips, 100 filters, 200 tubes, etc.
Characterizing flavor:	None, menthol, tobacco ⁶ , etc.
Additional properties ⁵ :	Wrapper material (e.g., wood, hemp, flax, etc.), etc.

⁷ Product properties for each component comprising the co-package are determined by the component itself (e.g., one set of rolling paper properties and one set of roll-your-own tobacco filler properties).

⁸ Each component should have the product properties according to the subcategory that the individual component would fall under.

⁹ Product properties are dependent on the product or component type, so some product properties may not be applicable.

SMOKELESS TOBACCO PRODUCTS

Category properties:

Consumption:	Placed in the oral or nasal cavity
Extent of heating:	None
Tobacco wrapper:	None or pouch material
Assembly:	No assembly required
Tobacco filler:	Solid (cut tobacco leaf, whole tobacco leaf, or ground tobacco leaf)

Loose Moist Snuff

Subcategory properties:

Consumption:	Placed in the oral or nasal cavity
Tobacco cut form:	Shredded or cut
Moisture:	Generally 20%-60%
Processing of tobacco:	Fermentation
Product form:	Loose

Product properties:

Package type:	Plastic can and lid, tin can and lid, plastic can with metal lid, etc.
Package quantity:	20 grams, 2 ounces, etc.
Tobacco cut size:	5 mm, 7 mm, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.
Additional properties ⁵ :	Green, premium, etc.

Portioned Moist Snuff

Subcategory properties:

Consumption:	Placed in the oral cavity
Tobacco cut form:	Shredded or cut
Moisture:	Generally 20%-60%
Processing of tobacco:	Fermentation
Product form:	Portioned (pouched, bound)

Product properties:

Package type:	Plastic can and lid, tin can and lid, plastic can with metal lid, etc.
Package quantity:	22.5 grams, 20 grams, etc.
Portion count:	15 pouches, 20 pieces, etc.
Portion mass:	1.5 grams/pouch, 1.0 grams/piece, etc.
Portion length ¹⁰ :	15 mm, 20 mm, etc.
Portion width ¹⁰ :	10 mm, 15 mm, etc.
Portion thickness ¹⁰ :	5 mm, 7 mm, etc.
Tobacco cut size:	5 mm, 7 mm, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.
Additional properties ⁵ :	Fine cut, long cut, premium, etc.

Loose Snus

Subcategory properties:

Consumption:	Placed in the oral or nasal cavity
Tobacco cut form:	Shredded or cut
Moisture:	Generally 20-30%
Processing of tobacco:	Pasteurization
Product form:	Loose

Product properties:

Package type:	Plastic can and lid, tin can and lid, plastic can with metal lid, etc.
Package quantity:	20 grams, 2 ounces, etc.
Tobacco cut size:	5 mm, 7 mm, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.
Additional properties ⁵ :	Premium, etc.

¹⁰ Per the October 21, 2015, memorandum (see Appendix 2), a tobacco product is uniquely identified if all of the product properties are provided or if all of the product products are provided except only two of the following properties are provided: portion length, portion width, and portion thickness.

Portioned Snus

Subcategory properties:

Consumption:	Placed in the oral or nasal cavity
Tobacco cut form:	Shredded or cut
Moisture:	Generally 20-30%
Processing of tobacco:	Pasteurization
Product form:	Portioned (pouched, bound)

Product properties:

Package type:	Plastic can and lid, tin can and lid, plastic can with metal lid, etc.
Package quantity:	22.5 grams, 20 grams, etc.
Portion count:	15 pouches, 20 pieces, etc.
Portion mass:	1.5 grams/pouch, 1.0 grams/piece, etc.
Portion length ¹⁰ :	15 mm, 20 mm, etc.
Portion width ¹⁰ :	10 mm, 15 mm, etc.
Portion thickness ¹⁰ :	5 mm, 7 mm, etc.
Tobacco cut size:	5 mm, 7 mm, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.
Additional properties ⁵ :	White, natural, slimline, premium, etc.

Loose Dry Snuff

Subcategory properties:

Consumption:	Placed in the oral or nasal cavity
Tobacco cut form:	Particulate, powdered, ground
Moisture:	Generally ≤10%
Processing of tobacco:	Fermentation
Product form:	Loose

Product properties:

Package type:	Plastic can and lid, tin can and lid, plastic can with metal lid, etc.
Package quantity:	20 grams, 2 ounces, etc.
Tobacco cut size:	0.05 mm, 0.07 mm, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.
Additional properties ⁵ :	Green, premium, etc.

Dissolvable

Subcategory properties:

Consumption:	Placed in the oral cavity
Tobacco cut form:	Particulate, powdered, ground
Moisture:	Generally $\leq 10\%$
Processing of tobacco:	Fermentation
Product form:	Portioned

Product properties:

Package type:	Plastic can and lid, tin can and lid, plastic can with metal lid, etc.
Package quantity:	22.5 grams, 20 grams, etc.
Portion count:	15 sticks, 20 pieces, etc.
Portion mass:	1.5 grams/stick, 1.0 grams/piece, etc.
Portion length ¹⁰ :	10 mm, 15 mm, etc.
Portion width ¹⁰ :	5 mm, 8 mm, etc.
Portion thickness ¹⁰ :	3 mm, 4 mm, etc.
Tobacco cut size:	0.05 mm, 0.07 mm, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.
Additional properties ⁵ :	Wooden dowel, sponge, stick, strip, tablet, etc.

Loose Chewing Tobacco

Subcategory properties:

Consumption:	Placed in the oral or nasal cavity
Tobacco cut form:	Whole leaf, pieces of leaf
Moisture:	Generally 10-25%
Processing of tobacco:	Fermentation
Product form:	Non-portioned

Product properties:

Package type:	Bag, pouch, wrapped, etc.
Package quantity:	20 grams, 3 ounces, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.
Tobacco cut size:	0.05 mm, 0.07 mm, etc.
Additional properties ⁵ :	Extra-long, premium, loose leaf, plug, twist, etc.

Portioned Chewing Tobacco

Subcategory properties:

Consumption:	Placed in the oral or nasal cavity
Tobacco cut form:	Whole leaf, pieces of leaf
Moisture:	Generally 10-25%
Processing of tobacco:	Fermentation
Product form:	Portioned

Product properties:

Package type:	Plastic can and lid, tin can and lid, plastic can with metal lid, etc.
Package quantity:	20 grams, etc.
Portion count:	10 bits, etc.
Portion mass:	2 grams/bit, etc.
Portion length ¹⁰ :	8 mm, 10 mm, etc.
Portion width ¹⁰ :	6 mm, 8 mm, etc.
Portion thickness ¹⁰ :	5 mm, 7 mm, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.
Additional properties ⁵ :	Green, premium, bit, pellet, etc.

Smokeless Co-Package

Subcategory properties:

Consumption:	Placed in the oral or nasal cavity
Tobacco cut form:	Whole leaf, pieces of leaf, shredded, cut, particulate, powdered, ground
Moisture:	Any moisture
Processing of tobacco:	Any (fermentation or pasteurization)
Product form:	Loose or portioned

Product properties¹¹:

Component ⁸ :	Any combination of loose moist snuff, portioned moist snuff, loose snus, portioned snus, loose dry snuff, dissolvable, loose chewing tobacco, and portioned chewing tobacco
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¹¹ Product properties for each component comprising the co-package are determined by the component itself (e.g., one set of portioned snus properties and one set of loose snus properties).

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Other

Subcategory properties:

Consumption:	Placed in the oral or nasal cavity
Tobacco cut form:	Whole leaf, pieces of leaf, shredded, cut, particulate, powdered, ground
Moisture:	Any moisture
Processing of tobacco:	Any (fermentation or pasteurization)
Product form:	Loose or portioned

Product properties⁹:

Package type:	Box, bag, can, etc.
Package quantity:	20 grams, 22.5 grams, 3 ounces, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, tobacco, etc.
Additional properties ⁵ :	Green, premium, wooden dowel, sponge, white, natural, slimline, etc.

ENDS (Electronic Nicotine Delivery System)

Category properties:

Consumption:	Puffed and/or inhaled
Extent of heating:	Non-combusted or not applicable
Tobacco wrapper:	None or material other than paper or tobacco leaf
Assembly:	No assembly required or user assembly of multiple ENDS products
Tobacco filler:	None or liquid

Open E-Liquid

Subcategory properties:

Extent of heating:	Non-combusted
Assembly:	User assembly with open e-cigarette
Tobacco filler:	Liquid
Refillable:	Yes or No

Product properties:

Package type:	Bottle, box, etc.
Package quantity:	1 bottle, 5 bottles, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.
E-liquid volume:	10 ml, etc.
Nicotine concentration:	0, 0.2 mg/ml, 0.4 mg/ml, 1%, 0.2 mg/bottle, etc.
PG/VG ratio:	Not applicable (N/A), 0/100, 50/50, 100/0, etc.
Additional properties ⁵ :	Regular, high, heavy, premium, etc.

Closed E-Liquid

Subcategory properties:

Extent of heating:	Non-combusted
Assembly:	User assembly with open e-cigarette
Tobacco filler:	Liquid
Refillable:	No

Product properties:

Package type:	Cartridge
Package quantity:	1 cartridge, 5 cartridges, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.
E-liquid volume:	10 ml, etc.
Nicotine concentration:	0, 0.2 mg/ml, 0.4 mg/ml, 1%, 0.2 mg/bottle, etc.
PG/VG ratio:	N/A, 0/100, 50/50, 100/0, etc.
Additional properties ⁵ :	Regular, high, heavy, premium, compatible with XXX e-cigarette, etc.

Closed E-Cigarette

Subcategory properties:

Extent of heating:	Non-combusted
Tobacco filler:	Liquid
Assembly:	No user assembly ¹²
Refillable:	No ¹³

Product properties:

Package type:	Box, none, plastic clamshell, etc.
Package quantity:	1 e-cigarette, 5 e-cigarettes, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.
Length:	100 mm, 120 mm, etc.
Diameter:	6 mm, 8 mm, etc.
Nicotine concentration:	0, 0.2 mg/ml, 0.4 mg/ml, 1%, 0.2 mg/e-cig, etc.
PG/VG ratio:	N/A, 0/100, 50/50, 100/0, etc.
E-liquid volume:	2 ml, 5 ml, etc.
Wattage:	100 W, 200 W, etc.
Battery capacity:	100 mAh, 200 mAh, etc.
Additional properties ⁵ :	Automatic, manual, USB, disposable, premium, etc.

¹² Changing a cartridge or battery is not considered user assembly

¹³ May include products with replaceable cartridges (not refillable cartridges)

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Open E-Cigarette

Subcategory properties:

Extent of heating:	Not applicable
Tobacco filler:	None
Assembly:	User assembly with e-liquid
Refillable:	Yes

Product properties:

Package type:	Box, none, plastic clamshell, etc.
Package quantity:	1 e-cigarette, etc.
Characterizing flavor:	None, etc.
Length:	100 mm, 200 mm, etc.
Diameter:	8 mm, 14 mm, etc.
E-liquid volume:	2 ml, 5 ml, etc.
Wattage:	100 W, 200 W, etc.
Battery capacity:	100 mAh, 200 mAh, etc.
Additional properties ⁵ :	N/A, variable voltage, temp sensor, etc.

ENDS Component

Subcategory properties:

Extent of heating:	Non-combusted or not applicable
Tobacco filler:	None
Assembly:	User assembly with e-cigarette components and e-liquid
Refillable:	Yes or no

Product properties¹⁴:

Package type:	Box, none, plastic clamshell, etc.
Package quantity:	1 e-cigarette, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, tobacco ⁶ , etc.
Additional properties ⁵ :	N/A, variable voltage, temp sensor, premium, etc.

ENDS Co-Package

Subcategory properties:

Extent of heating:	Non-combusted or not applicable
Tobacco filler:	Liquid
Assembly:	User assembly with other components contained in product
Refillable:	Yes or no

Product properties¹⁵:

Component ⁸ :	Any combination of e-liquid, closed e-cigarette, e-cigarette components, and open e-cigarette
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¹⁴ Product properties are dependent on the component type, so some product properties may not be applicable.

¹⁵ Product properties for each component comprising the co-package are determined by the component itself (e.g., one set of e-liquid properties and one set of open e-cigarette properties).

Unique Identification of Tobacco Products

Other

Subcategory properties:

Extent of heating:	Non-combusted or not applicable
Tobacco filler:	None or liquid
Assembly:	No assembly required or user assembly with other ENDS products
Refillable:	Yes or no

Product properties⁹:

Package type:	Box, none, plastic clamshell, etc.
Package quantity:	1 e-cigarette, 5 bottles, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, tobacco ⁶ , etc.
Additional properties ⁵ :	N/A, variable voltage, temp sensor, premium, etc.

CIGARS

Category properties:

Consumption:	Puffed and/or inhaled
Extent of heating:	Combusted or not applicable
Tobacco wrapper:	None, tobacco leaf, or tobacco-containing sheet
Assembly:	No user assembly required or user assembly with other cigar products
Tobacco filler:	None or solid (cut tobacco leaf or whole tobacco leaf)

Filtered, Sheet-Wrapped Cigar

Subcategory properties:

Extent of heating:	Combusted
Tobacco filler:	Solid (cut tobacco leaf)
Tobacco wrapper:	Tobacco-containing sheet
Assembly:	No user assembly required
Filtration:	Contains a filter

Product properties:

Package type:	Hard pack, soft pack, clam shell, etc.
Package quantity:	20 filtered cigars, 25 filtered cigars, etc.
Characterizing flavor:	None, menthol, etc.
Length:	89 mm, 100 mm, etc.
Diameter:	6 mm, 8.1 mm, etc.
Ventilation:	None ⁴ , 10%, 25%, etc.
Additional properties ⁵ :	Charcoal filter, dark, spiral wrapped, green, premium, etc.

Unfiltered, Sheet-Wrapped Cigar

Subcategory properties:

Extent of heating:	Combusted
Tobacco filler:	Solid (cut tobacco leaf)
Tobacco wrapper:	Tobacco-containing sheet
Assembly:	No user assembly required
Filtration:	Does not contain a filter

Product properties:

Package type:	Box, film sleeve, etc.
Package quantity:	1 cigar, 5 cigarillos, etc.
Characterizing flavor:	None, menthol, cherry, etc.
Length:	100 mm, 140 mm etc.
Diameter:	8 mm, 10 mm, etc.
Tip:	None, wood tips, plastic tips, etc.
Additional properties ⁵ :	Spiral wrapped, dark, green, premium, etc.

Leaf-Wrapped Cigar

Subcategory properties:

Extent of heating:	Combusted
Tobacco filler:	Solid (cut tobacco leaf)
Tobacco wrapper:	Tobacco leaf
Assembly:	No user assembly required
Filtration:	Does not contain a filter

Product properties:

Package type:	Box, film sleeve, none, etc.
Package quantity:	1 cigar, 5 cigars, etc.
Characterizing flavor:	None, whiskey, etc.
Length:	150 mm, 200 mm, etc.
Diameter:	8 mm, 10 mm, etc.
Wrapper material:	Burley tobacco leaf, Connecticut shade grown tobacco leaf, etc.
Additional properties ⁵ :	Cuban, premium, binder material (e.g., reconstituted tobacco sheet, tobacco leaf), etc.

Unique Identification of Tobacco Products

Cigar Component

Subcategory properties:

Extent of heating:	Not applicable
Tobacco filler:	None
Tobacco wrapper:	Tobacco-containing paper
Assembly:	User assembly with cigar tobacco filler
Filtration:	Contains a filter or does not contain a filter

Product properties¹⁴:

Package type:	Box, booklet, etc.
Package quantity:	10 wrappers, 20 leaves, etc.
Characterizing flavor:	None, menthol, cherry, etc.
Additional properties ⁵ :	Cuban, sweetened, premium, wrap, tip, etc.

Cigar Tobacco Filler

Subcategory properties:

Extent of heating:	Not applicable
Tobacco filler:	Solid (cut tobacco leaf)
Tobacco wrapper:	Tobacco leaf or tobacco-containing paper
Assembly:	User assembly with cigar wrapper
Filtration:	N/A

Product properties:

Package type:	Bag, pouch, etc.
Package quantity:	20 grams, 16 ounces, etc.
Characterizing flavor:	None, tobacco, menthol, cherry, etc.
Tobacco cut size:	15 cuts per inch, etc.
Additional properties ⁵ :	Green, premium, cavendish, perique, etc.

Unique Identification of Tobacco Products

Cigar Co-Package

Subcategory properties:

Extent of heating:	Combusted or not applicable
Tobacco filler:	Solid (cut tobacco leaf)
Tobacco wrapper:	Tobacco leaf or tobacco-containing sheet
Assembly:	User assembly with components contained in product
Filtration:	Contains a filter or does not contain a filter

*Product properties*¹⁶:

Component ⁸ :	Any combination of filtered, sheet-wrapped cigar; unfiltered, sheet-wrapped cigar; leaf-wrapped cigar; cigar wrapper; and cigar tobacco filler
--------------------------	--

Other

Subcategory properties:

Extent of heating:	Combusted or not applicable
Tobacco filler:	None or solid (cut tobacco leaf)
Tobacco wrapper:	Tobacco leaf or tobacco-containing sheet
Assembly:	No user assembly required or user assembly of multiple cigar products
Filtration:	Contains a filter or does not contain a filter

*Product properties*⁹:

Package type:	Box, booklet, etc.
Package quantity:	1 cigar, 5 cigars, 20 leaves, 16 grams, etc.
Characterizing flavor:	None, menthol, cherry, etc.
Additional properties ⁵ :	Cuban, sweetened, premium, cavendish, perique, etc.

¹⁶ Product properties for each component comprising the co-package are determined by the component itself (e.g., one set of cigar tobacco filler properties and one set of cigar wrapper properties).

PIPE TOBACCO PRODUCTS

Category properties:

Consumption:	Puffed and/or inhaled
Extent of heating:	Combusted or non-combusted
Tobacco wrapper:	None
Assembly:	User assembly of multiple pipe tobacco products
Tobacco filler:	None or solid (cut tobacco leaf)

Pipe

Subcategory properties:

Extent of heating:	Not applicable
Tobacco filler:	None
Assembly:	User assembly with pipe tobacco filler

Product properties:

Package type:	Box, none, etc.
Package quantity:	1 pipe, etc.
Length:	200 mm, 300 mm, etc.
Diameter:	25 mm, etc.
Characterizing flavor:	None, menthol, Cavendish, cherry, etc.
Additional properties ⁵ :	Sandblasted, hand carved, smooth, etc.

Pipe Tobacco Filler

Subcategory properties:

Extent of heating:	Combusted
Tobacco filler:	Solid (cut tobacco leaf)
Assembly:	User assembly with a pipe

Product properties:

Package type:	Bag, pouch, etc.
Package quantity:	20 grams, 16 ounces, etc.
Characterizing flavor:	None, menthol, cavendish, cherry, etc.
Additional properties ⁵ :	Green, Premium, etc.

Unique Identification of Tobacco Products

Pipe Component

Subcategory properties:

Extent of heating:	Not applicable
Tobacco filler:	None
Assembly:	User assembly with other pipe tobacco products

*Product properties*¹⁴:

Package type:	Box, bag, none, etc.
Package quantity:	1 bowl, 1 stem, 100 filters, etc.
Characterizing flavor:	None, cherry, etc.
Additional properties ⁵ :	Green, Premium, bowl, stem, filter, etc.

Pipe Co-Package

Subcategory properties:

Extent of heating:	Not applicable
Tobacco filler:	None or solid (cut tobacco leaf)
Assembly:	User assembly with components contained in product

*Product properties*¹⁷:

Component ⁸ :	Any combination of pipe, pipe components, and pipe tobacco filler
--------------------------	---

¹⁷ Descriptive properties for each component comprising the co-package are determined by the component itself (e.g., one set of pipe properties and one set of pipe tobacco filler properties).

Unique Identification of Tobacco Products

Other

Subcategory properties:

- Extent of heating: Combusted or not applicable
- Tobacco filler: None or solid (cut tobacco leaf)
- Assembly: User assembly with other pipe tobacco products

*Product properties*⁹:

- Package type: Box, bag, none, etc.
- Package quantity: 1 pipe, 1 bowl, 1 stem, 100 filters, etc.
- Characterizing flavor: None, cherry, etc.
- Additional properties⁵: Unknown

WATERPIPE TOBACCO PRODUCTS

Category properties:

Consumption:	Puffed and/or inhaled
Extent of heating:	Combusted or not applicable
Tobacco Wrapper:	None
Assembly:	User assembly of multiple waterpipe tobacco products
Tobacco filler:	None or solid (cut tobacco leaf)

Waterpipe

Subcategory properties:

Extent of heating:	Not applicable
Tobacco filler:	None
Assembly:	User assembly with waterpipe tobacco filler
Heat Source:	No

Product properties:

Package type:	Box, none, etc.
Package quantity:	1 waterpipe, etc.
Characterizing flavor:	None, etc.
Length:	200 mm, 500 mm, etc.
Width:	100 mm, 300 mm, etc.
Number of hoses:	1, 2, 4, etc.
Additional properties ⁵ :	Green, Premium, etc.

Waterpipe Tobacco Filler

Subcategory properties:

Extent of heating:	Non-combusted
Tobacco filler:	Solid (cut tobacco leaf)
Assembly:	User assembly with a waterpipe
Heat Source:	No

Product properties:

Package type:	Bag, pouch, etc.
Package quantity:	20 grams, 16 ounces, etc.
Characterizing flavor:	None, tobacco, menthol, apple, etc.
Additional properties ⁵ :	Green, premium, etc.

Waterpipe Heat Source

Subcategory properties:

Extent of heating:	Not applicable
Tobacco filler:	None
Assembly:	User assembly with waterpipe and waterpipe tobacco filler
Heat source:	Yes

Product properties:

Package type:	Box, film sleeve, bag, none, etc.
Package quantity:	150 g, 680 g, etc.
Characterizing flavor:	None, menthol, apple, etc.
Portion count:	20 fingers, 10 discs, 1 base, etc.
Portion mass:	15 grams/finger, 10 grams/brick, etc.
Portion length ¹⁸ :	40 mm, 100 mm, etc.
Portion width ¹⁸ :	10 mm, 40 mm, etc.
Portion thickness ¹⁸ :	10 mm, 40 mm, etc.
Source of energy:	Charcoal, battery, electrical, etc.
Additional properties ⁵ :	USB, green, premium, etc.

Waterpipe Component

Subcategory properties:

Extent of heating:	Not applicable
Tobacco filler:	None
Assembly:	User assembly with other waterpipe tobacco products
Heat Source:	No

Product properties¹⁴:

Package type:	Box, bag, none, etc.
Package quantity:	1 base, 1 bowl, 1 hose, 10 mouthpieces, etc.
Characterizing flavor:	None, cherry, etc.
Additional properties ⁵ :	Green, Premium, etc.

¹⁸ Similar to October 21, 2015 memorandum for smokeless tobacco products. A tobacco product is uniquely identified if all of the product properties are provided or if all of the product properties are provided except only two of the following properties are provided: portion length, portion width, and portion thickness. If the portion mass is provided as well as two of the three properties of portion length, portion width, or portion thickness, the third property (either portion length, portion width, or portion thickness) is negligible.

Unique Identification of Tobacco Products

Waterpipe Co-Package

Subcategory properties:

Extent of heating:	Non-combusted or not applicable
Tobacco filler:	None or solid (cut tobacco leaf)
Assembly:	User assembly with other waterpipe tobacco products
Heat Source:	No

*Product properties*¹⁹:

Component ⁸ :	Any combination of waterpipe, waterpipe tobacco filler, waterpipe heat source, and waterpipe component
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Other

Subcategory properties:

Extent of heating:	Non-combusted or not applicable
Tobacco filler:	None or solid (cut tobacco leaf)
Assembly:	User assembly with other waterpipe tobacco products
Heat Source:	Yes or No

*Product properties*⁹:

Package type:	Box, bag, none, etc.
Package quantity:	1 base, 1 bowl, 1 hose, 10 mouthpieces, etc.
Characterizing flavor:	None, cherry, etc.
Additional properties ⁵ :	Unknown

¹⁹ Product properties for each component comprising the co-package are determined by the component itself (e.g., one set of waterpipe tobacco filler properties and one set of waterpipe properties).

APPENDIX 1 – June 2, 2015, Memo



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
Silver Spring, MD 20993

MEMORANDUM

From: Matthew R. Holman, Ph.D.
Director, Division of Product Science (DPS)
Office of Science (OS) Digitally signed by Matthew R. Holman -S
Date: 2015.06.02 10:25:20 -04'00'

Through: Cristi Stark, M.S.
Associate Director, Science Policy
Office of Science Digitally signed by Cristi L. Stark -S
Date: 2015.06.02 10:38:47 -04'00'

To: Regulatory Health Project Managers (RHPMs)
RHPM Branch II
Office of Science

Subject: Unique Identification of New and Predicate Products

When FDA sends letters to applicants regarding an SE Report, it is important that the applicable tobacco products within the SE Report are uniquely identified. Unique identification is necessary for a new tobacco product so that FDA understands what product should undergo review and receive an order. In addition, unique identification for a predicate product is required so that FDA understands what product should be compared to the new product for a determination of substantial equivalence. After receipt of an SE Report, the first communication from FDA to the applicant includes information clearly identifying the basics of the report: (1) submission tracking number (STN), (2) submission date, (3) FDA receipt date, and (4) unique identification of the new tobacco product (including the category, subcategory, name, and other characteristics necessary to identify the new tobacco product). In addition to the acknowledgement letter, when issuing a decision of SE or NSE, the order letter also clearly identifies both the new and predicate tobacco products under which the scientific finding was made.

I issued a memorandum on October 20, 2014, that identifies the key product properties which are needed to uniquely identify new and predicate tobacco products. However, with additional experience reviewing SE Reports since that date, it has become clear that some of the information in the October 20, 2014, memorandum requires modifications. For example, under the smokeless tobacco category, dissolvable/strip, dissolvable/tablet, and dissolvable/stick should be combined into a single "dissolvable" subcategory. The purpose of this memorandum is to update October 20, 2014, memorandum and identify the information currently needed to uniquely identify new and predicate tobacco products.

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CIGARETTES

Combusted, Filtered

Categorical properties:

Consumption:	Puffed and inhaled
Assembly:	No assembly required by user
Wrapper:	Cellulose-based paper
Intended heat:	Combusted (with lighter or match)
Filtration:	Contains a filter

Descriptive properties:

Package type:	Hard pack, soft pack, clam shell, etc.
Package quantity:	20 cigarettes, 25 cigarettes, etc.
Length:	King, 89 mm, 100 mm, etc.
Diameter:	Regular, 6 mm, 8.1 mm, etc.
Ventilation:	None, 10%, 25%, etc.
Characterizing Flavor ¹ :	None, Tobacco, Menthol

Combusted, Non-filtered

Categorical properties:

Consumption:	Puffed and inhaled
Assembly:	No assembly required by user
Wrapper:	Cellulose-based paper
Intended heat:	Combusted (with lighter or match)
Filtration:	Does not contain a filter

Descriptive properties:

Package type:	Hard pack, soft pack, clam shell, etc.
Package quantity:	20 cigarettes, 25 cigarettes, etc.
Length:	King, 89 mm, 100 mm, etc.
Diameter:	Regular, 6 mm, 8.1 mm, etc.
Ventilation:	None, 10%, 25%, etc.
Characterizing Flavor:	None, Tobacco, Menthol

¹ as indicated in product name and descriptors

Non-Combusted

Categorical properties:

Consumption:	Puffed and inhaled
Assembly:	No assembly required by user
Wrapper:	Cellulose-based paper or other
Intended heat:	Heated, Other (Tobacco is not combusted)
Filtration:	Does or does not contain a filter

Descriptive properties:

Package type:	Hard pack, soft pack, clam shell, etc.
Package quantity:	20 cigarettes, 25 cigarettes, etc.
Length:	King, 89 mm, 100 mm, etc.
Diameter:	Regular, 6 mm, 8.1 mm, etc.
Ventilation:	None, 10%, 25%, etc.
Characterizing Flavor:	None, Tobacco, Menthol

Bidi and Other Combusted

Categorical properties:

Consumption:	Puffed and inhaled
Assembly:	No assembly required by user
Wrapper:	Leaf-based paper (typically Tendu leaf for bidis)
Intended heat:	Combusted (with lighter or match)
Filtration:	Does not contain a filter (typically)

Descriptive properties:

Package type:	Hard pack, soft pack, clam shell, etc.
Package quantity:	20 cigarettes, 25 cigarettes, etc.
Length:	King, 89 mm, 100 mm, etc.
Diameter:	Regular, 6 mm, 8.1 mm, etc.
Ventilation:	None, 10%, 25%, etc.
Characterizing Flavor:	None, Tobacco, Menthol

ROLL-YOUR-OWN TOBACCO PRODUCTS

Roll-Your-Own Tobacco Filler

Categorical properties:

Consumption:	Puffed and inhaled
Assembly:	Unassembled – final assembly by user
Contains:	Tobacco only
Intended heat:	Combusted (with lighter or match)
Filtration:	Does not include filter

Descriptive properties:

Package type:	Bag, pouch, etc.
Package quantity:	20 grams, 16 ounces, etc.
Characterizing Flavor:	None, tobacco, menthol

Rolling Paper

Categorical properties:

Consumption:	Puffed and inhaled
Assembly:	Unassembled – final assembly by user
Contains:	No tobacco
Intended heat:	Combusted (with lighter or match)
Filtration:	Does not include filter

Descriptive properties:

Package type:	Box, booklet, etc.
Package quantity:	50 sheets, 200 papers, etc.
Length:	79 mm, 100 mm, 110 mm, etc.
Width:	28 mm, 33 mm, 45 mm, etc.
Characterizing Flavor:	None, tobacco, menthol

Filtered Cigarette Tube

Categorical properties:

Consumption:	Puffed and inhaled
Assembly:	Partially assembled – final assembly by user
Contains:	No tobacco
Intended heat:	Combusted (with lighter or match)
Filtration:	Includes filter

Descriptive properties:

Package type:	Bag, box, etc.
Package quantity:	100 tubes, 200 tubes, etc.
Length:	King, 89 mm, 100 mm, etc.
Diameter:	Regular, 6 mm, 8.1 mm, etc.
Ventilation:	None, 10%, 25%, etc.
Characterizing Flavor:	None, tobacco, menthol

Non-Filtered Tube

Categorical properties:

Consumption:	Puffed and inhaled
Assembly:	Partially assembled – final assembly by user
Contains:	No tobacco
Intended heat:	Combusted (with lighter or match)
Filtration:	Does not include filter

Descriptive properties:

Package type:	Bag, box, etc.
Package quantity:	100 tubes, 200 tubes, etc.
Length:	King, 89 mm, 100 mm, etc.
Diameter:	Regular, 6 mm, 8.1 mm, etc.
Characterizing Flavor:	None, tobacco, menthol

Unique Identification of New and Predicate Tobacco Products

Filter

Categorical properties:

Consumption:	Puffed and inhaled
Assembly:	Unassembled – final assembly by user
Contains:	No tobacco
Intended heat:	Combusted (with lighter or match)
Filtration:	Includes filter

Descriptive properties:

Package type:	Bag, box, etc.
Package quantity:	100 filters, 200 filters, etc.
Length:	8 mm, 12 mm, etc.
Diameter:	6 mm, 8.1 mm, etc.
Characterizing Flavor:	None, tobacco, menthol

Roll-Your-Own Bundle

Categorical properties:

Consumption:	Puffed and inhaled
Assembly:	Assembly required by user
Contains:	Tobacco and other components, bundled components
Components:	Any combination of: roll-your-own tobacco filler, rolling paper, filtered cigarette tube, filter, non-filtered tube, and paper tip
Intended heat:	Combusted (with lighter or match)
Filtration:	Includes filter or does not include filter

Descriptive properties²:

Components:	Roll-your-own tobacco filler, rolling paper, etc.
Package type:	Can, bag, box, etc.
Package quantity:	One bag, two booklets, etc.
Length:	8 mm, 12 mm, 89 mm, 100 mm, etc. (if applicable for component)
Width:	28 mm, 33 mm, 45 mm, etc. (if applicable for component)
Diameter:	6 mm, 8.1 mm, etc. (if applicable for component)
Ventilation:	None, 10%, 25%, etc. (if applicable for component)
Characterizing Flavor:	None, tobacco, menthol

² Must include descriptive properties for each component comprising the bundle (e.g., one set of properties for rolling paper and one set of properties for roll-your-own tobacco filler)

Unique Identification of New and Predicate Tobacco Products

Paper Tip

Categorical properties:

Consumption:	Puffed and inhaled
Assembly:	Assembly required by user
Contains:	No tobacco
Intended heat:	Combusted (with lighter or match)
Filtration:	Does not include filter

Descriptive properties:

Package type:	Bag, box, etc.
Package quantity:	200 tips, 275 tips, etc.
Length:	12 mm, 15 mm, etc.
Characterizing Flavor:	None, tobacco, menthol

SMOKELESS TOBACCO PRODUCTS

Loose Moist Snuff

Categorical properties:

Consumption:	Placed in the oral cavity
Processing of tobacco:	Fermentation
Tobacco cut form:	Shredded or cut
Moisture:	20%-60%
Product form:	Loose

Descriptive properties:

Package type:	Plastic can and lid, tin can and lid, plastic can with metal lid, etc.
Package quantity:	20 grams, 2 ounces, etc.
Tobacco cut size:	5 mm, 7 mm, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.

Portioned Moist Snuff

Categorical properties:

Consumption:	Placed in the oral cavity
Processing of tobacco:	Fermentation
Tobacco cut form:	Shredded or cut
Moisture:	20%-60%
Product form:	Pouched, bound (e.g., ReadyCut, NeatCut)

Descriptive properties:

Package type:	Plastic can and lid, tin can and lid, plastic can with metal lid, etc.
Package quantity:	22.5 grams, 20 grams, etc.
Portion count:	15 pouches, 20 pieces, etc.
Portion mass:	1.5 grams/pouch, 1.0 grams/piece, etc.
Portion length:	15 mm, 20 mm, etc.
Portion width:	10 mm, 15 mm, etc.
Portion thickness:	5 mm, 7 mm, etc.
Tobacco cut size:	5 mm, 7 mm, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.

Unique Identification of New and Predicate Tobacco Products

Loose Snus

Categorical properties:

Consumption:	Placed in the oral or nasal cavity
Processing of tobacco:	Pasteurization
Tobacco cut form:	Shredded or cut
Moisture:	Generally 20-30%
Product form:	Loose

Descriptive properties:

Package type:	Plastic can and lid, tin can and lid, plastic can with metal lid, etc.
Package quantity:	20 grams, 2 ounces, etc.
Tobacco cut size:	5 mm, 7 mm, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.

Portioned Snus

Categorical properties:

Consumption:	Placed in the oral cavity
Processing of tobacco:	Pasteurization
Tobacco cut form:	Shredded or cut
Moisture:	Generally 20-30%
Product form:	Pouched, bound

Descriptive properties:

Package type:	Plastic can and lid, tin can and lid, plastic can with metal lid, etc.
Package quantity:	22.5 grams, 20 grams, etc.
Portion count:	15 pouches, 20 pieces, etc.
Portion mass:	1.5 grams/pouch, 1.0 grams/piece, etc.
Portion length:	15 mm, 20 mm, etc.
Portion width:	10 mm, 15 mm, etc.
Portion thickness:	5 mm, 7 mm, etc.
Tobacco cut size:	5 mm, 7 mm, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.

Loose Dry Snuff

Categorical properties:

Consumption:	Placed in the oral or nasal cavity
Processing of tobacco:	Fermentation
Tobacco cut form:	Particulate, powdered, ground
Moisture:	Generally $\leq 10\%$
Product form:	Loose

Descriptive properties:

Package type:	Plastic can and lid, tin can and lid, plastic can with metal lid, etc.
Package quantity:	20 grams, 2 ounces, etc.
Tobacco cut size:	0.05 mm, 0.07 mm, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.

Dissolvable

Categorical properties:

Consumption:	Placed in the oral or nasal cavity
Processing of tobacco:	Fermentation
Tobacco cut form:	Particulate, powdered, ground
Moisture:	Generally $\leq 10\%$
Product form:	Stick, strip, tablet (e.g., orb), etc.

Descriptive properties:

Package type:	Plastic can and lid, tin can and lid, plastic can with metal lid, etc.
Package quantity:	22.5 grams, 20 grams, etc.
Product form:	tablet, stick, strip, etc.
Portion count:	15 sticks, 20 pieces, etc.
Portion mass:	1.5 grams/stick, 1.0 grams/piece, etc.
Portion length:	10 mm, 15 mm, etc.
Portion width:	5 mm, 8 mm, etc.
Portion thickness:	3 mm, 4 mm, etc.
Tobacco cut size:	0.05 mm, 0.07 mm, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.

Loose Chewing Tobacco

Categorical properties:

Consumption:	Placed in the oral cavity
Processing of tobacco:	Fermentation
Tobacco cut form:	Whole leaf, pieces of leaf
Moisture:	Generally 10-25%
Product form:	Loose leaf, plug (brick), twist

Descriptive properties:

Package type:	Bag, pouch, wrapped, etc.
Package quantity:	20 grams, 3 ounces, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.

Portioned Chewing Tobacco

Categorical properties:

Consumption:	Placed in the oral cavity
Processing of tobacco:	Fermentation
Tobacco cut form:	Whole leaf; pieces of leaf
Moisture:	Generally 10-25%
Product form:	Bits (pellets), etc.

Descriptive properties:

Package type:	Plastic can and lid, tin can and lid, plastic can with metal lid, etc.
Package quantity:	20 grams, etc.
Product form:	Bits, etc.
Portion count:	10 bits, etc.
Portion mass:	2 grams/bit, etc.
Portion length:	8 mm, 10 mm, etc.
Portion width:	6 mm, 8 mm, etc.
Portion thickness:	5 mm, 7 mm, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.

Smokeless Bundle

Categorical properties:

Consumption:	Placed in the oral or nasal cavity
Processing of tobacco:	Fermentation or pasteurization
Tobacco cut form:	Shredded, cut, particulate, powdered, ground, etc.
Contains:	Bundled components
Components:	Any combination of: loose moist snuff, portioned moist snuff, loose dry snuff, dissolvable, loose chewing tobacco, portioned chewing tobacco
Moisture:	Range – depending on the type of component included
Product form:	Loose, pouched, bound (e.g., Ready Cut), bits, stick, strip, tablet (e.g., orb), etc.

Descriptive properties³:

Components:	Tablets, strips, orbs, bits, plug, loose leaf, etc.
Package type:	Plastic can and lid, tin can and lid, plastic can with metal lid, etc.
Package quantity:	22.5 grams, 20 grams, etc.
Product form:	Tablet, stick, strip, etc. (if applicable for component)
Portion count:	15 sticks, 20 pieces, etc. (if applicable for component)
Portion mass:	1.5 grams/stick, 1.0 grams/piece, etc. (if applicable for component)
Portion length:	10 mm, 15 mm, etc. (if applicable for component)
Portion width:	5 mm, 8 mm, etc. (if applicable for component)
Portion thickness:	3 mm, 4 mm, etc. (if applicable for component)
Tobacco cut size:	0.05 mm, 0.07 mm, etc.
Characterizing flavor:	None, menthol, cherry, wintergreen, etc.

³ Must include all applicable descriptive properties for each component comprising the bundle (e.g., one set of properties for dissolvable tablet and one set of properties for dissolvable strips)

APPENDIX 2- October 21, 2015, Memo



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
Silver Spring, MD 20993

MEMORANDUM

From: Matthew R. Holman, Ph.D.
Director, Division of Product Science
Office of Science
Digitally signed by Matthew R. Holman -S
Date: 2015.10.21 14:20:50 -04'00'

Through: Cristi Stark, M.S.
Associate Director, Science Policy
Office of Science
Digitally signed by Cristi L. Stark -S
Date: 2015.10.21 14:23:23 -04'00'

To: File

Subject: Unique Identification of Portioned Moist Snuff and Snus Products

Background

On June 2, 2015, I drafted a memo to outline the properties needed to uniquely identify new and predicate tobacco products in SE Reports. We have received SE Reports for portioned moist snuff or snus products that have not provided all of the properties identified in the June 2015 memo. These SE Reports have led to reconsideration of the properties needed to uniquely identify portioned moist snuff and snus products.

Discussion

The June 2015 memo identifies the following descriptive properties for portioned moist snuff and snus products:

1. Package type
2. Portion count
3. Portion mass¹
4. Portion length
5. Portion width
6. Portion thickness
7. Tobacco cut size

¹ Portion mass is for the tobacco filler only.

Unique Identification of Portioned Moist Snuff and Snus

8. Characterizing flavor

If an applicant provides all of these descriptive properties for a new or predicate tobacco product, the product would be uniquely identified. However, it is also possible to uniquely identify a portioned moist snuff or snus product with only seven of these descriptive properties if *both* of the following criteria are met:

1. Portion mass is provided
2. Two of the three portion dimensions are provided:
 - a. Portion length
 - b. Portion width
 - c. Portion thickness

By specifying portion mass along with two other portion dimensions, the third portion dimension is essentially non-variable. For example, if the portion mass, length, and width are specified for a given product, then the portion thickness is unlikely to vary for the product. In other words, although the portion thickness is not known for the product, the product could not exist with multiple portion thicknesses. Therefore, providing portion mass plus two of the three portion dimensions (along with other specified properties) allows unique identification of portioned moist snuff and snus products.

Conclusion and Recommendation

For new and predicate products in SE Reports that are portioned moist snuff or snus, all of the following properties must be specified by the applicant in order to uniquely identify the products:

1. Package type
2. Portion count
3. Portion mass
4. Tobacco cut size
5. Characterizing flavor
6. Two or three of the following:
 - a. Portion length
 - b. Portion width
 - c. Portion thickness

APPENDIX 3 - Definitions

Unique Identification of Tobacco Products

Airflow Opening Size – *The airflow opening is the maximum area of the two-dimensional space that allows or limits the air flow into the ENDS.*

Battery Capacity - *The standard of measurement that describes the total amount of energy that the battery can deliver over one hour. It is measured as mAh.*

Characterizing Flavor - *For each tobacco product, this is indicated by chemical composition, olfactory response, tobacco product labeling, or a combination of any of the three. For an acceptance review it may be noted as described by the submitter/manufacturer. However, any order issued will note the characterizing flavor as determined by FDA.*

Component or part – *Component or part means any software or assembly of materials intended or reasonably expected: 1) to alter or affect the tobacco product’s performance, composition, constituents or characteristics; or 2) to be used with or for the human consumption of a tobacco product. The term excludes anything that is an accessory of a tobacco product.*

Diameter– *The diameter is the maximum distance representing a straight line passing from side-to-side through the center of a circular product (distance across a circle). Diameter can be calculated as circumference divided by π (3.14).*

Extent of Heat – *Refers to the extent of heating the tobacco filler (filler can be heated-combusted, heated-not combusted, or not heated).*

E-Liquid Volume – *The three dimensional capacity of a bottle, cartridge, or tank containing an e-liquid. Volume is expressed in milliliters.*

Length – *The maximum measurement or extent of the tobacco product from end to end along the longest edge.*

Nicotine Concentration - *The amount of nicotine present in an e-liquid on a mass per volume basis (e.g., mg/ml).*

Number of Hoses – *Quantity of hoses present on a waterpipe connecting the waterpipe bowl to a mouthpiece.*

Package Quantity – *The amount (expressed as number of pieces), mass, or volume of tobacco product in a container closure system.*

Package Type – *The type of container closure system (e.g., soft pack, plastic can with plastic lid).*

Portion Length – *The measurement in millimeters of an individual unit of use from end to end along the longest edge.*

Portion Mass – *The quantity of matter (measured in milligrams) of an individual unit of use.*

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Portion Quantity – *The number of individual units of use for a tobacco product contained in a single container closure system.*

Portion Thickness – *The measurement in millimeters of the individual unit of use in the direction perpendicular to the length and the width.*

Portion Width – *The measurement in millimeters of the individual unit of use from side to side along the second longest edge.*

PG/VG Ratio - *Propylene Glycol (PG) is used as a base carrier for the nicotine and/or flavoring. Vegetable Glycerin is an alternative to Propylene Glycol. PG/VG ratio is the concentration of the base carrier that PG expressed as ml/ml relative to the concentration of the base carrier that VG expressed as ml/ml.*

Source of Energy – *How the tobacco product is heated, combusted, or powered.*

Tobacco Cut Size –*The physical dimensions of the tobacco in the tobacco product. This could be expressed as a single value or as fraction size by percentage, etc.*

Ventilation –*The percentage of the mainstream smoke that is represented by fresh air dilution through small holes in the paper wrapping the filter, (e.g., tipping paper, plug wrap, etc.).*

Wattage – *In an ENDS product, the measure of electrical power. For variable wattage ENDS products, it is the maximum wattage.*

Width - *The maximum measurement in millimeters of the tobacco product from side to side perpendicular to length.*

Wrapper Material –. *Materials are assemblies of ingredients, including additives, to form the tobacco product or components or parts. The wrapper is the outermost part of a cigar. It is made up of tobacco leaf or sheet and is the outermost leaf or sheet around the cigar*