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## 1 FINISHED ZYN PRODUCTS

ZYN® is a 0.4-gram tobacco-free sealed pouch containing nicotine bitartrate dihydrate and food-grade stabilizer, fillers, pH adjusters, sweetener, and flavorings. ZYN pouch material consists of (b) (4), and (b) (4). ZYN is manufactured in 10 flavors, each at 3-mg nicotine and 6-mg nicotine strengths. The Food and Drug Administration's (FDA's) Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, Guidance for Industry (June 2019) recommends the premarket tobacco application (PMTA) contain "an identifying reference to any tobacco product standard under Section 907 (of the Federal Food, Drug, and Cosmetic Act [FD&C Act]), which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard.

There are no tobacco product standards issued under the FD&C Act Section 907 that are currently applicable to ZYN products. Accordingly, there is no action to be taken by Swedish Match in order to ensure that the products described in this application comply with Section 907.

### 1.1 Formulations and Intended Function of Each Ingredient

The formulation of each strength of ZYN across all flavors uses the same ingredients, except for the flavor-specific components. The pouch material is identical for both strengths across all flavors. The ingredients common to all flavors of ZYN finished product (3 mg and 6 mg), the Chemical Abstracts Service (CAS) numbers, and the ingredient function are presented in Table 1. Detailed formulations with the specific amounts of each ingredient are listed in Section 2.3 of this document. The flavor components of each ZYN product, their grades, their unique identifiers, and their CAS numbers are presented in [Section G.4 Product Composition Summary, Section 1.1](#). Information on the flavor manufacturers is found in [Section G.3 Product Manufacturing and Controls Summary, Section 1.2](#).

**Table 1 ZYN Finished Product Common Ingredients and Their Intended Function**

Ingredients	Grade	Unique ID	CAS Number	Function
Acesulfame K	Food grade	(b) (4)	(4)	Sweetener
(b) (4)	(b) (4)			Processing aid
Hydroxypropyl cellulose	USP			Stabilizer
Maltitol	Food grade			Filler
Microcrystalline cellulose	(b) (4)			Filler
Nicotine bitartrate dihydrate	USP <sup>a</sup>			Other (key ingredient)
Pouch material	USA FDA CFR 21 176.170 & 177.2260			Fiber
Sodium bicarbonate	Food grade			pH adjuster

Ingredients	Grade	Unique ID	CAS Number	Function
Sodium carbonate	Food grade	(b) (4)		pH adjuster
(b) (4)			(b) (4)	Processing aid

Source: [Section G.3 Product Manufacturing and Controls Summary, Section 1.4](#)

CAS=Chemical Abstracts Service; CFR=Code of Federal Regulations; EP=European Pharmacopoeia; FDA=Food and Drug Administration; ID=identification; JP=Japanese Pharmacopoeia; NA=not applicable; NF=National Formulary; USA=United States of America; USP=United States Pharmacopoeia.

<sup>a</sup> Meets the purity criteria for nicotine in the USP monograph.

Table 2 through [Table 4](#) provide unique identification information and hyperlinks for the packaged 10 flavors, each with 2 strengths, variants of the ZYN finished products.

**Table 2 Swedish Match ZYN, Cool Mint, Peppermint, and Spearmint Product Information**

Parameter	Cool Mint 3 mg	Cool Mint 6 mg	Peppermint 3 mg	Peppermint 6 mg	Spearmint 3 mg	Spearmint 6 mg
Unique ID SE (SKU)	8105	8106	8107	8108	8109	8110
Unique ID US	900510	900520	901510	901520	902510	902520
Packaging	<a href="#">Section E.1 Product Packaging and Labeling</a>					
Flavor Components	<a href="#">Section G.4 Product Composition Summary, Section 1.1, Table 2</a>					
Nicotine content (%)	(b) (4)					

ID=identifier; SE=Sweden; SKU=stock keeping unit; US=United States.

**Table 3 Swedish Match ZYN, Wintergreen, Citrus, and Coffee Product Information**

Parameter	Wintergreen 3 mg	Wintergreen 6 mg	Citrus 3 mg	Citrus 6 mg	Coffee 3 mg	Coffee 6 mg
Unique ID SE (SKU)	8111	8112	8122	8123	8124	8125
Unique ID US	903510	903520	907510	907520	904510	904520
Packaging	<a href="#">Section E.1 Product Packaging and Labeling</a>					
Flavor components	<a href="#">Section G.4 Product Composition Summary, Section 1.1, Table 2</a>					
Nicotine content (%)	(b) (4)					

ID=identifier; SE=Sweden; SKU=stock keeping unit; US=United States.

**Table 4 Swedish Match ZYN, Cinnamon, Smooth, Chill, and Fresh Product Information**

	Cinnamon 3 mg	Cinnamon 6 mg	Smooth 3 mg	Smooth 6 mg	Chill 3 mg	Chill 6 mg	Fresh 3 mg	Fresh 6 mg
Unique ID SE (SKU)	8128	8129	8134	8135	8136	8137	8140	8141
Unique ID US	906510	906520	914510	914520	920510	920520	921510	921520
Packaging	<a href="#">Section E.1 Product Packaging and Labeling</a>							
Flavor components	<a href="#">Section G.4 Product Composition Summary, Section 1.1, Table 2</a>							
Nicotine content (%)	<b>(b) (4)</b>							

ID=identifier; SE=Sweden; SKU=stock keeping unit; US=United States.

**1.2 ZYN Finished Product Component Specifications****1.2.1 Nicotine bitartrate dihydrate (Unique ID **(b) (4)**) Specifications**

The nicotine bitartrate dihydrate used in all flavors of ZYN product is produced by **(b) (4)**. While there is no United States Pharmacopeia (USP) monograph for nicotine bitartrate dihydrate, the nicotine bitartrate dihydrate used in the manufacture of ZYN meets the purity criteria of the USP and European Pharmacopoeia for nicotine. For details of the nicotine bitartrate dihydrate manufacturer and specifications, refer to the **(b) (4)** Tobacco Products Master File number **(b) (4)**. The **(b) (4)** letter of authorization is located in [Section A5 Other, TPMF Letters of Authorization](#).

**1.2.2 Common Ingredients Specifications**

The common ingredients used in all flavors of ZYN products are all food grade or pharmaceutical grade materials that comply with Swedish Match requirements and compendial requirements, where applicable.

**1.2.3 Flavor Component Specification**

The flavor compounds used in all flavors of ZYN products are food-grade ingredients and comply with Swedish Match requirements and compendial requirements, where applicable.

**1.2.4 Pouch Material (Unique ID **(b) (4)**) Specification**

ZYN pouch material consists of **(b) (4)** and **(b) (4)**. The exact composition of the pouch paper is a trade secret of the vendor.

The physical properties of the pouch wrapping material and a drawing of a representative filled pouch for ZYN products are provided in [Section G.4 Product Composition Summary, Section 1.1.1.4](#).

### **1.3 Product Use**

The consumer places the ZYN pouch between the upper lip and gum. The pouch is held between the lip and gum for up to 60 minutes and then discarded. When used as directed, the pouch allows the nicotine to dissolve in saliva and be absorbed through the mucous membrane of the mouth. The instructions for product use are included on the can side label and the roll label. Refer to [Section G.2 Product Design Summary, Section 1.3](#) for a representative label for the ZYN product use.

### **1.4 Consumer Modifications and Product Variations**

The quantities of nicotine bitartrate dihydrate in ZYN 3 mg and 6 mg products are calculated to achieve a nicotine content of 3 mg and 6 mg, respectively. Swedish Match does not reasonably expect consumers to be able to modify the nicotine content of ZYN pouches, based on the granulated form of the pouch contents. Potential modifications could include opening the pouch and attempting to consume the pouch contents through means inconsistent with the labeling. However, due to the design, Swedish Match considers the potential for consumer modification of ZYN to be low.

There is minimal variation between the ten flavors and two strengths of ZYN as described in [Section G.2 Product Design Summary, Section 1.1](#). Both the 3 mg and 6 mg strengths of each flavor contain the same ingredients and differ only in the amount of nicotine bitartrate dihydrate. The various flavors of ZYN contain the same pouch and common ingredients and differ only in the flavor components.



## 2 ZYN PRODUCTS MANUFACTURING

### 2.1 Design

ZYN is a 0.4-gram tobacco-free sealed pouch containing nicotine bitartrate dihydrate, food grade fillers, flavorings, pH adjusters, stabilizer, and sweetener for the purpose of oral absorption of nicotine. ZYN pouch material consists of (b) (4) and (b) (4) (b) (4). ZYN is manufactured in 10 unique flavors, each at 3-mg nicotine and 6-mg nicotine strengths. ZYN finished product ingredients and intended function, as well as each of the flavor components, are summarized in [Section G.2 Product Design Summary, Section 1.1, Table 1](#) and [Table 2](#).

The primary packaging of ZYN finished product consists of a 21 Code of Federal Regulations (CFR) 177.1520(c)-compliant child-resistant, polypropylene can and safety lid, which is designed to contain 15 pouches. For shipping and retail sale, the secondary packaging consists of ZYN cans that are wrapped in rolls containing five cans per roll using low-density polyethylene shrink film. ZYN rolls are packed in corrugated cardboard cases, which serve as tertiary packaging, and are sealed with clear carton sealing tape composed of polypropylene and containing 18 rolls, or 90 cans per case. Packaging components are summarized in [Section G.2 Product Design Summary, Section 1.2](#).

### 2.2 Manufacturing and Controls

Facilities involved in the manufacturing, packaging, storage, and distribution of ZYN product and its components are listed in [Section G.3 Product Manufacturing and Controls Summary, Table 1, Table 2, and Table 3](#). The testing facilities and the type of testing performed at each facility are listed in [Section G.3 Product Manufacturing and Controls Summary, Section 1.3, Table 4](#). A list of relevant standard operating procedures relating to the Swedish Match Quality Management System is provided in [Section G.3 Product Manufacturing and Controls Summary, Section 1.5.3, Table 16](#).

The manufacturing process for the ZYN product is composed of two processing stages, namely finished powder granulate (FPG) (bulk) processing, and packing of finished product pouches. The same process is used for all flavors of ZYN, as the flavor formulations are similar except for the flavoring components. The FPG production process including the process flow diagram is described in [Section G.3 Product Manufacturing and Controls Summary, Section 1.5.1.1](#), and the pouch packing process with the process flow diagram is described in [Section G.3 Product Manufacturing and Controls Summary, Section 1.5.1.2](#). The master batch records for all ZYN products can be found in [Section H.1.4.3 Swedish Match Corporate Applicable Procedures](#).

### 2.3 Chemical Compositions (Formulations)

The chemical formulations representing each ZYN product are summarized in [Table 5](#) through [Table 14](#) and [Section G.3 Product Manufacturing and Controls Summary, Section 1.4](#).

**Table 5 ZYN Cool Mint Formulation 3 mg (8105), 6 mg (8106)**

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	(4)
(b) (4)	Processing aid		
Hydroxypropyl cellulose <sup>3</sup>	Stabilizer		
Maltitol <sup>1</sup>	Filler		
Microcrystalline cellulose	Filler		
Nicotine bitartrate dihydrate <sup>2</sup>	Other (key ingredient)		
Pouch material	Fiber		
Sodium carbonate <sup>3</sup>	pH adjuster		
Sodium bicarbonate <sup>3</sup>	pH adjuster		
(b) (4)	Processing aid		
(b) (4)	Flavor		

Source: [Section H.1.1.1.1 Cool Mint \(8105\)](#), [Section H.1.1.1.2 Cool Mint \(8106\)](#)<sup>1</sup> The amount added is adjusted to achieve a target pouch weight of 0.4 g.<sup>2</sup> The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) nicotine per pouch.<sup>3</sup> The amount added is adjusted to achieve a target pH of (b) (4).**Table 6 ZYN Peppermint Formulation 3 mg (8107), 6 mg (8108)**

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	(4)
(b) (4)	Processing aid		
Hydroxypropyl cellulose <sup>3</sup>	Stabilizer		
Maltitol <sup>1</sup>	Filler		
Microcrystalline cellulose	Filler		
(b) (4)	Flavor		
Nicotine bitartrate dihydrate <sup>2</sup>	Other (key ingredient)		
Pouch material	Fiber		
Sodium carbonate <sup>3</sup>	pH adjuster		
Sodium bicarbonate <sup>3</sup>	pH adjuster		
(b) (4)	Processing aid		



Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
(b) (4)	Flavor	(b) (4)	

Source: [Section H.1.1.1.1 Peppermint \(8107\)](#), [Section H.1.1.1.2 Peppermint \(8108\)](#)

<sup>1</sup> The amount added is adjusted to achieve a target pouch weight of 0.4 g.

<sup>2</sup> The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) nicotine per pouch.

<sup>3</sup> The amount added is adjusted to achieve a target pH of (b) (4).

**Table 7 ZYN Spearmint Formulations 3 mg (8109), 6 mg (8110)**

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	
(b) (4)	Processing aid		
Hydroxypropyl cellulose <sup>3</sup>	Stabilizer		
Maltitol <sup>1</sup>	Filler		
Microcrystalline cellulose	Filler		
(b) (4)	Flavor		
Nicotine bitartrate dihydrate <sup>2</sup>	Other (key ingredient)		
Pouch material	Fiber		
Sodium carbonate <sup>3</sup>	pH adjuster		
Sodium bicarbonate <sup>3</sup>	pH adjuster		
(b) (4)	Processing aid		
	Flavor		

Source: [Section H.1.1.1.1 Spearmint \(8109\)](#), [Section H.1.1.1.2 Spearmint \(8110\)](#)

<sup>1</sup> The amount added is adjusted to achieve a target pouch weight of 0.4 g.

<sup>2</sup> The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) nicotine per pouch.

<sup>3</sup> The amount added is adjusted to achieve a target pH of (b) (4).

**Table 8 ZYN Wintergreen Formulations 3 mg (8111), 6 mg (8112)**

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	
(b) (4)	Processing aid		
Hydroxypropyl cellulose <sup>3</sup>	Stabilizer		
Maltitol <sup>1</sup>	Filler		
Microcrystalline cellulose	Filler		
Nicotine bitartrate dihydrate <sup>2</sup>	Other (key ingredient)		
Pouch material	Fiber		

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Sodium carbonate <sup>3</sup>	pH adjuster	(b) (4)	(4)
Sodium bicarbonate <sup>3</sup>	pH adjuster		
(b) (4)	Processing aid		
	Flavor		

Source: [Section H.1.1.1.1 Wintergreen \(8111\)](#), [Section H.1.1.1.2 Wintergreen \(8112\)](#)

<sup>1</sup> The amount added is adjusted to achieve a target pouch weight of 0.4 g.

<sup>2</sup> The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) nicotine per pouch.

<sup>3</sup> The amount added is adjusted to achieve a target pH of (b) (4).

**Table 9 ZYN Citrus Formulations 3 mg (8122), 6 mg (8123)**

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	(4)
(b) (4)	Processing aid		
Hydroxypropyl cellulose <sup>3</sup>	Stabilizer		
Maltitol <sup>1</sup>	Filler	(b) (4)	(4)
Microcrystalline cellulose	Filler		
Nicotine bitartrate dihydrate <sup>2</sup>	Other (key ingredient)		
Pouch material	Fiber	(b) (4)	(4)
Sodium carbonate <sup>3</sup>	pH adjuster		
Sodium bicarbonate <sup>3</sup>	pH adjuster		
(b) (4)	Processing aid	(b) (4)	(4)
	Flavor		

Source: [Section H.1.1.1.1 Citrus \(8122\)](#), [Section H.1.1.1.2 Citrus \(8123\)](#)

<sup>1</sup> The amount added is adjusted to achieve a target pouch weight of 0.40 g.

<sup>2</sup> The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) of nicotine per pouch

<sup>3</sup> The amount added is adjusted to achieve a target pH of (b) (4).

**Table 10 ZYN Coffee Formulations 3 mg (8124), 6 mg (8125)**

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	(4)
(b) (4)	Processing aid		
Hydroxypropyl cellulose <sup>3</sup>	Stabilizer		
Maltitol <sup>1</sup>	Filler	(b) (4)	(4)
Microcrystalline cellulose	Filler		
Nicotine bitartrate dihydrate <sup>2</sup>	Other (key ingredient)		

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Pouch material	Fiber	(b) (4)	(4)
Sodium carbonate <sup>3</sup>	pH adjuster		
Sodium bicarbonate <sup>3</sup>	pH adjuster		
(b) (4)	Processing aid		
	Flavor		

Source: [Section H.1.1.1.1 Coffee \(8124\)](#), [Section H.1.1.1.2 Coffee \(8125\)](#)

<sup>1</sup> The amount added is adjusted to achieve a target pouch weight of 0.4 g.

<sup>2</sup> The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) nicotine per pouch.

<sup>3</sup> The amount added is adjusted to achieve a target pH of (b) (4).

**Table 11 ZYN Cinnamon Formulations 3 mg (8128), 6 mg (8129)**

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	(4)
(b) (4)	Processing aid		
Hydroxypropyl cellulose <sup>3</sup>	Stabilizer		
Maltitol <sup>1</sup>	Filler		
Microcrystalline cellulose	Filler		
Nicotine bitartrate dihydrate <sup>2</sup>	Other (key ingredient)		
Pouch material	Fiber		
Sodium carbonate <sup>3</sup>	pH adjuster		
Sodium bicarbonate <sup>3</sup>	pH adjuster		
(b) (4)	Processing aid		
	Flavor		

Source: [Section H.1.1.1.1 Cinnamon \(8128\)](#), [Section H.1.1.1.2 Cinnamon \(8129\)](#)

<sup>1</sup> The amount added is adjusted to achieve a target pouch weight of 0.4 g.

<sup>2</sup> The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) nicotine per pouch.

<sup>3</sup> The amount added is adjusted to achieve a target pH of (b) (4).

**Table 12 ZYN Smooth Formulations 3 mg (8134), 6 mg (8135)**

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	(4)
(b) (4)	Processing aid		
Hydroxypropyl cellulose <sup>3</sup>	Stabilizer		
Maltitol <sup>1</sup>	Filler		
Microcrystalline cellulose	Filler		

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Nicotine bitartrate dihydrate <sup>2</sup>	Other (key ingredient)	(b) (4)	(4)
Pouch material	Fiber		
Sodium carbonate <sup>3</sup>	pH adjuster		
Sodium bicarbonate <sup>3</sup>	pH adjuster		
(b) (4)	Processing aid		

Source: [Section H.1.1.1.1 Smooth \(8134\)](#), [Section H.1.1.1.2 Smooth \(8135\)](#)

<sup>1</sup> The amount added is adjusted to achieve a target pouch weight of 0.4 g.

<sup>2</sup> The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) nicotine per pouch.

<sup>3</sup> The amount added is adjusted to achieve a target pH of (b) (4).

**Table 13 ZYN Chill Formulations 3 mg (8136), 6 mg (8137)**

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	(4)
(b) (4)	Processing aid		
Hydroxypropyl cellulose <sup>3</sup>	Stabilizer		
Maltitol <sup>1</sup>	Filler		
Microcrystalline cellulose	Filler		
(b) (4)	Flavor		
Nicotine bitartrate dihydrate <sup>2</sup>	Other (key ingredient)		
Pouch material	Fiber		
Sodium carbonate <sup>3</sup>	pH adjuster		
Sodium bicarbonate <sup>3</sup>	pH adjuster		
(b) (4)	Processing aid		

Source: [Section H.1.1.1.1 Chill \(8136\)](#), [Section H.1.1.1.2 Chill \(8137\)](#)

<sup>1</sup> The amount added is adjusted to achieve a target pouch weight of 0.4 g.

<sup>2</sup> The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) nicotine per pouch.

<sup>3</sup> The amount added is adjusted to achieve a target pH of (b) (4).

**Table 14 ZYN Fresh Formulations 3 mg (8140), 6 mg (8141)**

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	(4)
(b) (4)	Processing aid		
Hydroxypropyl cellulose <sup>3</sup>	Stabilizer		
Maltitol <sup>1</sup>	Filler		
Microcrystalline cellulose	Filler		
Nicotine bitartrate dihydrate <sup>2</sup>	Other (key ingredient)		
Pouch material	Fiber		
Sodium carbonate <sup>3</sup>	pH adjuster		
Sodium bicarbonate <sup>3</sup>	pH adjuster		
(b) (4)	Processing aid		
	Flavor		

Source: [Section H.1.1.1.1 Fresh \(8140\)](#), [Section H.1.1.1.2 Fresh \(8141\)](#)

<sup>1</sup> The amount added is adjusted to achieve a target pouch weight of 0.4 g.

<sup>2</sup> The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) nicotine per pouch.

<sup>3</sup> The amount added is adjusted to achieve a target pH of (b) (4).

## 2.4 Analytical Evaluation

### 2.4.1 ZYN Routine Release Testing

#### 2.4.1.1 ZYN Pouch Material

The routine release specifications and analytical procedures used for testing the pouch material (basis weight, thickness sheet, and air permeability), and the testing results for three batches of the pouch material are presented in [Section G.3 Product Manufacturing and Controls Summary, Section 2.5](#).

#### 2.4.1.2 ZYN Finished Product Release

The finished product release specifications for the ZYN products (all flavors and strengths) are provided in [Section G.3 Product Manufacturing and Controls Summary, Section 2.6.2, Table 22](#) and [Table 23](#). Analytical procedures and analytical procedure validation used for finished product release and stability (ie, nicotine content, pH, moisture content, and individual pouch weight) are discussed in [Section G.3 Product Manufacturing and Controls Summary, Section 2.6.2.1](#) to [Section 2.6.2.8](#). Summaries of the finished product routine batch analysis results, including average, range, and standard deviation for the data set tested for each flavor and strength of the ZYN products, are presented in [Section G.3 Product Manufacturing and Controls Summary, Section 2.6.4](#).

#### 2.4.2 ZYN Finished Product Characterization

The analytical procedures used for the characterization of the Swedish Match ZYN finished products are presented in [Section G.3 Product Manufacturing and Controls Summary, Section 2.6.3.1](#) to [Section 2.6.3.24](#). The analytical procedures have been fully validated and shown to be suitable for the characterization of the ZYN products.

The characterization testing was performed on at least three different batches of each of the 20 ZYN products. Characterization results for each ZYN product are summarized in the appendix of [Section G.5 Nonclinical Evaluation Summary](#).

Characterization testing will not be performed for routine product release but will be performed annually. If a change is proposed that has the potential to affect the quality of the product, characterization testing will be performed on the post-change product to demonstrate that the product characteristics have not changed.

Characterization testing of the ZYN product included harmful or potentially harmful constituents (HPHCs) testing, water activity, and microbiological testing.

The HPHCs that were analyzed and will be subject to annual analysis include the following: tobacco specific nitrosamines, nitrite, aldehydes, nicotine and nicotine-related compounds, N-nitrosodimethylamine, benzo(a)pyrene and polyaromatic hydrocarbons, heavy metals, (b) (4), (b) (4), and (b) (4).

Analytes not subject to annual testing include the HPHCs acrylamide, ethyl carbamate, mycotoxins, radioisotopes (Po-210, U-235, U-238); as well as the selected analytes, such as fermentable sugars, polysaccharides, and agrochemicals.

#### 2.4.3 ZYN Finished Product Stability

Stability studies were performed to establish the shelf life of the 20 ZYN products intended for the PMTA-regulated market and are summarized in [Section G.3 Product Manufacturing and Controls Summary, Section 2.7.2](#). Each ZYN finished product was stored in cans (primary container) (b) (4) RH and analyzed at (b) (4) and (b) (4) weeks. The proposed shelf life for all ZYN products is (b) (4).

#### 2.5 Environmental Assessment

The environmental assessment was prepared in accordance with 21 CFR 25.20 and 21 CFR 25.40, which are the FDA's regulation implementing the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.). This environmental assessment is located in [Section F Product Environmental Assessment](#).

The finding of No Significant Impact for the environmental assessment of the Products is recommended. No mitigation measures are recommended.



### 3 PACKAGING

#### 3.1 Packaging Components and Intended Function of Each Component

ZYN bulk powder is held in intermediate bulk storage containers which are suitable for food products and meet the requirements of 21 CFR 177.1520. For full details of the bulk storage container and closure, refer to [Section H.1.1.2.1 Bulk Container Closure System](#).

ZYN is manufactured as a quantity of 15 pouches contained in a 21 CFR 177.1520(c)-compliant polypropylene can, incorporating a certified child-resistant safety lid made of polypropylene. For details of the ZYN finished product container, including diagrams, refer to [Section G.4 Product Composition Summary, Section 1.3.1](#). For details of the can labeling, refer to [Section E.1 Product Packaging and Labeling](#).

For shipping and retail sale, ZYN cans are wrapped in rolls containing five cans per roll, using low-density polyethylene shrink film. ZYN rolls are packed in corrugated cardboard cases containing 18 rolls per case, for a total of 90 cans per case. Refer to [Section G.4 Product Composition Summary, Section 1.3.2](#) and [Section 1.3.3](#) for a complete description of the secondary and tertiary container systems, respectively.

#### 3.2 Assessment of Child-Resistant Packaging

An assessment of reclosable child-resistant packaging (CR Snuff Container 159-1) used for ZYN was performed on nursery school-age children and senior adults in accordance with 16 CFR 1700.20. (b) (4)

summary of the assessment tests and the results are presented in [Section G.3 Product Manufacturing and Controls Summary, Section 2.9](#). Refer to [Section H.1.2.5 Child-Resistant Packaging Report](#) for further details.