

Listing of Ingredients in Tobacco Products

(Revised)*

Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to <http://www.regulations.gov>. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with Docket No. [FDA-2009-D-0524].

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

Additional copies are available online at <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>. You may send an e-mail request to smallbiz.tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000.

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See additional PRA statement in section IV of the guidance

* This is the third edition of this guidance, which originally issued in November 2009. Revisions are noted by date at the end of the guidance.

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Listing of Ingredients in Tobacco Products

Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance document is intended to assist persons making tobacco product ingredient submissions to FDA. This guidance is intended for manufacturers and importers of cigarettes, cigarette tobacco, roll your own tobacco (RYO), smokeless tobacco, and those tobacco products subject to FDA's final rule, *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act* (81 FR 28974, May 10, 2016) (the deeming rule).

The guidance document explains, among other things:

- The statutory requirement to submit a list of all ingredients in tobacco products;
- Definitions;
- Who submits ingredient information;
- What information is included in the submissions;
- How to submit the information;

¹ This guidance was prepared by the Office of Regulations and the Office of Science in the Center for Tobacco Products at FDA.

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- 30 • When to submit the information; and
31 • FDA’s compliance policies.

32 FDA’s guidance documents, including this guidance, do not establish legally enforceable
33 responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should
34 be viewed only as recommendations, unless specific regulatory or statutory requirements are
35 cited. The use of the word *should* in Agency guidances means that something is suggested or
36 recommended, but not required.

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38

39 **II. BACKGROUND**

40
41 The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), enacted on
42 June 22, 2009, amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) and provides
43 FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco
44 products to protect the public health generally and to reduce tobacco use by minors (Pub. L. 111–
45 31, 123 Stat. 1776). Among its many provisions, the Tobacco Control Act added section 904 to
46 the FD&C Act (21 U.S.C. 387d), establishing requirements for tobacco product ingredient
47 submissions.

48
49 Cigarettes, cigarette tobacco, RYO, and smokeless tobacco were immediately covered by FDA’s
50 tobacco product authorities in chapter IX of the FD&C Act, including section 904, when the
51 Tobacco Control Act went into effect. As for other types of tobacco products, section 901(b) of
52 the FD&C Act (21 U.S.C. 387a(b)) grants FDA authority to deem those products subject to
53 chapter IX as well. Pursuant to that authority, FDA issued a proposed rule seeking to deem all
54 other products that meet the statutory definition of tobacco product, set forth in section 201(rr) of
55 the FD&C Act (21 U.S.C. 321(rr)) (except for accessories of those products) (79 FR 23142,
56 April 25, 2014).² After review and consideration of comments on the proposed rule, the final
57 rule published on May 10, 2016, with the effective date of August 8, 2016. As a result, all
58 products that meet the statutory definition of a tobacco product are subject to the tobacco product
59 authorities in chapter IX of the FD&C Act, including section 904, except those accessories not
60 made subject to FDA’s tobacco product authorities by the deeming rule.³

61
62 Section 904(a)(1) of the FD&C Act requires each tobacco product manufacturer or importer, or
63 agent thereof, to submit a listing of all ingredients, including tobacco, substances, compounds,

² Accessories of tobacco products subject to the deeming rule are explicitly excluded from the rule’s deeming provision.

³ Examples of currently marketed products that are subject to the deeming rule include: cigars, pipe tobacco, nicotine gel, certain dissolvable nicotine products, and electronic nicotine delivery systems (“ENDS”), including electronic cigarettes (also known as e-cigarettes or e-cigs), e-hookah, e-cigars, vape pens, personal vaporizers (also known as advanced personal vaporizers or APVs), electronic pipes, and nicotine-containing liquids, including the e-liquids used with ENDS products, among other products.

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64 and additives that are added by the manufacturer to the tobacco, paper, filter, or other part of
65 each tobacco product by brand and by quantity in each brand and subbrand. For cigarettes,
66 cigarette tobacco, RYO, and smokeless tobacco products on the market as of June 22, 2009, the
67 list of ingredients had to be submitted by December 22, 2009.⁴ For cigarettes, cigarette tobacco,
68 RYO, and smokeless tobacco products not on the market as of June 22, 2009, section 904(c)(1)
69 requires that the list of ingredients be submitted at least 90 days prior to delivery for introduction
70 into interstate commerce. Section 904(c) of the FD&C Act also requires submission of
71 information whenever any additive, or the quantity of any additive, is changed.

72 As described in the preamble to the deeming rule, for products other than cigarettes, cigarette
73 tobacco, RYO, and smokeless tobacco that are on the market as of August 8, 2016, FDA does
74 not intend to enforce the section 904(a)(1) ingredient listing submission requirement until 6
75 months after the effective date of the rule for most businesses and 12 months from the effective
76 date for small-scale tobacco product manufacturers (small-scale manufacturers).⁵ Under this
77 policy, FDA does not intend to enforce the ingredient list submission requirement with respect to
78 such products on the market as of August 8, 2016, until November 8, 2017, for businesses that
79 are not small-scale manufacturers, and May 8, 2018, for small-scale manufacturers (81 FR 28974
80 at 29008).

81 Additionally, FDA is extending the compliance deadlines with respect to products on the market
82 as of August 8, 2016, by an additional six months for tobacco product manufacturers and
83 importers in the areas impacted by recent natural disasters to May 8, 2018, and to November 8,
84 2018, for small-scale manufacturers impacted by recent natural disasters.⁶

85 As for those products that are first marketed after August 8, 2016, manufacturers must provide
86 the ingredient listing information required under section 901(a)(1) at least 90 days before the
87 product is delivered for introduction into interstate commerce, as was required for cigarettes,
88 cigarette tobacco, RYO, and smokeless tobacco first marketed after June 22, 2009 (section
89 904(c)(1)).

90 The failure to provide any information required by section 904 is a prohibited act under section
91 301(q)(1)(B) of the FD&C Act (21 U.S.C. 331(q)(1)(B)). In addition, under section

⁴ FDA did not enforce the December 22, 2009 deadline in situations where the ingredient list was submitted on or before June 22, 2010, pursuant to a compliance policy described in the November 2009 edition of this guidance.

⁵ For purposes of this compliance policy, FDA considers a *small-scale tobacco product manufacturer* to be a manufacturer of any regulated tobacco product that employs 150 or fewer full-time equivalent employees and has annual total revenues of \$5 million or less. FDA considers a manufacturer to include each entity that it controls, is controlled by, or is under common control with. To help make FDA's individual enforcement decisions more efficient, a manufacturer may voluntarily submit information regarding employment and revenues. In this guidance, we use the shortened term *small-scale manufacturer* to refer to *small-scale tobacco product manufacturer*.

⁶ For a complete list of the areas that have been impacted by recent natural disasters, please visit <https://www.fda.gov/TobaccoProducts/NewsEvents/ucm579265.htm>.

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92 903(a)(10)(A) of the FD&C Act (21 U.S.C. 387c(a)(10)(A)), a tobacco product is deemed
93 misbranded if there was any failure or refusal to comply with any requirement prescribed under
94 section 904. Violations relating to section 904 are subject to regulatory and enforcement action
95 by FDA, including, but not limited to, seizure and injunction.
96

97 **III. DISCUSSION**

98 **A. What Definitions Apply to This Guidance?**

99
100
101 FDA intends to use the following definitions to implement the ingredient listing requirements of
102 section 904 of the FD&C Act:
103

- 104 • **Accessory:** The term *accessory* means any product that is intended or reasonably expected to
105 be used with or for the human consumption of a tobacco product; does not contain tobacco
106 and is not made or derived from tobacco; and meets either of the following:

107 (1) Is not intended or reasonably expected to affect or alter the performance, composition,
108 constituents, or characteristics of a tobacco product; or

109 (2) Is intended or reasonably expected to affect or maintain the performance, composition,
110 constituents, or characteristics of a tobacco product but

111 (i) Solely controls moisture and/or temperature of a stored tobacco product; or

112 (ii) Solely provides an external heat source to initiate but not maintain combustion of a
113 tobacco product.
114

- 115 • **Additive:** The term *additive* means any substance the intended use of which results or
116 may reasonably be expected to result, directly or indirectly, in its becoming a component
117 or otherwise affecting the characteristic of any tobacco product (including any substances
118 intended for use as a flavoring or coloring or in producing, manufacturing, packing,
119 processing, preparing, treating, packaging, transporting, or holding), except that such
120 term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a
121 pesticide chemical. (section 900(1) of the FD&C Act (21 U.S.C. 387(1))
122

- 123 • **Component or part:** The term *component* or *part* means any software or assembly of
124 materials intended or reasonably expected:

125 (1) To alter or affect the tobacco product's performance, composition, constituents, or
126 characteristics; or

127 (2) To be used with or for the human consumption of a tobacco product.

128 Component or part excludes anything that is an accessory of a tobacco product.

129 FDA notes that *component* and *part* are separate and distinct terms within chapter IX of the
130 FD&C Act. However, for purposes of this guidance, FDA is using the terms *component* and
131 *part* interchangeably and without emphasizing the distinction. FDA may clarify the
132 distinctions between *component* and *part* in the future.
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- 134 • ***Finished tobacco product:*** The term *finished tobacco product* means a tobacco product,
135 including all components and parts, sealed in final packaging intended for consumer use
136 (e.g., filters or filter tubes sold separately to consumers or as part of kits).
137
- 138 • ***Importer:*** The term *importer* means any person who imports any tobacco product that is
139 intended for sale or distribution to consumers in the United States.
140
- 141 • ***Pouch:*** The term *pouch* means a permeable material, intended to be filled with pre-
142 portioned tobacco product and placed in the oral cavity with the tobacco product.
143
- 144 • ***Small-scale tobacco product manufacturer:*** The term *small-scale tobacco product*
145 *manufacturer* means a manufacturer of any regulated tobacco product that employs 150 or
146 fewer full-time equivalent employees and has annual total revenues of \$5 million or less.
147 FDA considers a manufacturer to include each entity that it controls, is controlled by, or is
148 under common control with.
149
- 150 • ***Tobacco product:*** The term *tobacco product* is defined in section 201(rr) of the FD&C Act,
151 which states in relevant part:
- 152 (1) The term “tobacco product” means any product made or derived from tobacco
153 that is intended for human consumption, including any component, part, or
154 accessory of a tobacco product (except for raw materials other than tobacco
155 used in manufacturing a component, part, or accessory of a tobacco product).”
156 (section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)).
- 157 (2) The term “tobacco product” does not include an article that is a drug under
158 [section 201(g)(1)], a device under [section 201(h)], or a combination product
159 [described in section 503(g) [of the FD&C Act (21 U.S.C. 353(g))].
- 160 Note that this definition includes accessories and components and parts of tobacco products,
161 whether they are made or derived from tobacco, and whether they are sold or distributed as
162 finished tobacco products.⁷
163
- 164 • ***Tobacco Product Manufacturer:*** The term *tobacco product manufacturer* means “any
165 person, including any repacker or relabeler, who (A) manufactures, fabricates, assembles,
166 processes, or labels a tobacco product; or (B) imports a finished tobacco product for sale
167 or distribution in the United States” (section 900(20) of the FD&C Act (21 U.S.C.
168 387(20)). Thus, the term is not limited to persons who manufacture products containing
169 tobacco, but includes anyone who manufactures any tobacco product as defined above.
170

⁷ However, and as explained above, accessories of tobacco products subject to the deeming rule are explicitly excluded from the rule’s deeming provision. Thus, although they meet the definition of tobacco product, such accessories are not currently subject to chapter IX of the FD&C Act (including section 904(a)(1)).

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B. Who Submits Ingredient Information?

The requirements under section 904(a)(1) apply to each “tobacco product manufacturer or importer.” We interpret this to mean that domestic manufacturers are to submit the required ingredient information for products they manufacture and that either the foreign manufacturer or the importer of the tobacco product is to submit the required ingredient information for imported tobacco products.

For tobacco products that are imported, the foreign manufacturer and the importer or importers of an imported product will need to work together to ensure that the ingredient information is submitted to FDA as required by section 904. If there is a failure or refusal to comply with the ingredient listing requirements, then — among other things — the product is deemed misbranded under section 903(a)(10)(A) and therefore subject to refusal of admission into the United States.

Submissions under section 904(c) are required to be made by the tobacco product manufacturer. An importer of a finished tobacco product for sale or distribution in the United States falls within the definition of a *manufacturer*. An importer that is not a manufacturer required to submit information or reports under section 904(c) may, however, submit the information as an agent on behalf of the manufacturer.

C. What Is FDA’S Compliance Policy for Regulated Tobacco Products?

At this time, with respect to all tobacco products, including cigarettes, cigarette tobacco, RYO, smokeless tobacco, as well as other tobacco products now regulated as a result of the deeming rule, FDA intends to enforce the ingredients submission requirements of section 904(a)(1) with respect to finished tobacco products only. FDA does not, at this time, intend to enforce these requirements with respect to products that are sold or distributed solely for further manufacturing.

As defined above, the term *finished tobacco product* means a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (e.g., filters or filter tubes sold separately to consumers or as part of kits).

Components and parts that are sold separately from other tobacco products are also finished tobacco products if they are sold in final packaging intended for consumer use. FDA intends to enforce the requirements for submission of ingredient information under section 904(a)(1) with respect to such products. Examples of components and parts that are sold or may be sold as finished tobacco products include pipe tobacco filler, filter tubes, e-cigarette batteries, and e-liquids, whether sold separately to consumers or as part of kits.

Based on our experience with cigarettes, cigarette tobacco, RYO and smokeless tobacco, we are amending our previous compliance policy. Under our previous policy, FDA intended to enforce the submission of the listing of ingredients requirements with respect to owners and operators engaged in the manufacture of tobacco, papers, filters, and pouches whether or not such products are for further manufacturing of, or for consumer use as, regulated tobacco products. However,

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216 FDA is announcing a change to that policy because we believe we can obtain the necessary
217 information about tobacco products components and parts through other means, such as
218 premarket applications for finished tobacco products and through the use of master files, as
219 explained in the guidance *Tobacco Product Master Files*.⁸ Additionally, we are aligning our
220 compliance policy for cigarettes, cigarette tobacco, RYO, and smokeless tobacco with the
221 products now regulated as a result of the deeming rule to reduce burden on industry. Should
222 FDA find that additional information is needed to protect the public health, the Agency may
223 reconsider this compliance policy. We intend to communicate any compliance policy changes
224 by guidance or rulemaking.

D. What Information Is Submitted With the List of Ingredients?

1. Manufacturer/Importer Identification

230 You should include the name and address of each tobacco product manufacturer (and importer,
231 where applicable) with your submission. You should also include the name and address of any
232 agent submitting ingredient information on behalf of a manufacturer or importer. FDA requests
233 that you also provide the following information to assist us in communicating with you:

- 234 • Your corporate email address;
- 235 • Your Data Universal Numbering System (D-U-N-S) number or other unique
236 identifier;⁹
- 237 • The facility establishment identifier (FEI) number assigned to your establishment
238 by FDA.¹⁰

2. Product Identification

240 Under section 904(a)(1) of the FD&C Act, tobacco product manufacturers or importers are
241 required to submit ingredient lists for “each tobacco product by brand and by quantity in each
242
243

⁸ This guidance is available on the CTP guidance Web page at
<http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

⁹ D-U-N-S numbers are proprietary to, and controlled by, Dun & Bradstreet. If the D-U-N-S number for a location has not been assigned, a business may obtain one for no cost directly from Dun & Bradstreet (<http://www.dnb.com>). Please note that registrants who wish to obtain a new D-U-N-S number should obtain one well in advance of FDA’s deadline, because it may take 30 days (or longer) to process a new number. Alternatively, you may elect to receive a D-U-N-S number within one business day by paying a fee. The business entity identifier recognized by the FDA Data Standards Council is the D-U-N-S number, and providing the site-specific D-U-N-S number for an entity will help prevent inaccuracies in FDA’s database.

¹⁰ You should use the same FEI number for this submission that you have used for prior ingredient listing submissions or establishment registration.

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244 brand and subbrand.” We interpret this to require that tobacco product manufacturers or
245 importers submit ingredient lists individually for tobacco products that differ in any way, other
246 than packaging differences that do not affect characteristics of the product. For example, if a soft
247 pack and a hard pack of cigarettes have different moisture contents, shelf lives, or ingredient
248 compositions (including ingredients introduced in packaging but known or reasonably expected
249 to become incorporated into the consumed product), they are considered to be distinct products
250 requiring separate ingredient lists for purposes of section 904(a)(1). Conversely, if the cigarettes
251 sold in different packaging configurations are identical, a single ingredient list should be
252 submitted for the product, noting the different packaging configurations.

253
254 For each ingredient list, clearly and uniquely identify the product by brand and subbrand,
255 including the type or category of tobacco product (e.g., cigarette, smokeless tobacco product,
256 cigar, ENDS, waterpipe tobacco product) and subcategory.¹¹ You are to include additional
257 identifiers (e.g., stock-keeping units (SKUs), Universal Product Codes (UPCs), and catalog
258 numbers) as needed to uniquely identify the brand and subbrand of the product.

259 3. *Ingredient Identification*

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261
262 Section 904(a)(1) of the FD&C Act sets forth the requirements for submission of ingredient
263 information. The statute requires a listing of all ingredients, including tobacco, substances,
264 compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or
265 other part of each tobacco product as of the date of submission. Ingredients must be specified for
266 each brand and subbrand of tobacco product.

267
268 FDA considers all ingredients added directly by, or at the direction of, the tobacco product
269 manufacturer to be added by the manufacturer. When the manufacturer knows or intends that an
270 ingredient is formed through a chemical reaction during tobacco product manufacturing, FDA
271 considers the resultant material to be an ingredient that is added by the manufacturer. Similarly,
272 when the manufacturer knows or intends that an ingredient added to any type of packaging will
273 become incorporated into the consumed product, that ingredient is considered to be added by the
274 manufacturer to the tobacco product.

275
276 Each listed ingredient is to be uniquely identified so as to distinguish it from similar or related
277 materials. The information necessary to uniquely identify an ingredient varies based upon the
278 type of ingredient as discussed below. For single chemical substances and complex purchased
279 ingredients, FDA also requests that you provide additional information, including the expected
280 functions of each ingredient. By asking for the functions of the ingredient, the agency requests
281 that you identify all expected functions of the ingredient in the final product. As examples, an
282 ingredient may function as a humectant, flavor, or chemo-sensory agent that affects perception of
283 mainstream or side-stream smoke.

¹¹ Lists of categories and subcategories are provided on Form 3742 and the eSubmitter submission template. See section III.E “How Do You Submit Ingredient Information.”

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a. Single Chemical Substance

Ingredients that are single chemical substances (e.g., sodium chloride, ammonium hydroxide), which may be purchased or prepared in-house and purified, are to be uniquely identified by using a unique scientific name or code, such as the FDA UNII (Unique Ingredient Identifiers) code, Chemical Abstracts Service (CAS) number, or International Union of Pure and Applied Chemistry (IUPAC) name. If you prepare a non-reactive mixture (e.g., a buffer) of single purified chemical substances, you are to report each of the single chemical substances in the mixture individually.

To further identify each single chemical substance, FDA requests that you provide the quality (e.g., percent purity, a published standard) of the ingredient, any internal identification number (e.g., SKU, product code) used within your company to reference the ingredient, and the expected function(s) of each ingredient.

We recommend using the FDA UNII code to uniquely identify single chemical substances. FDA's Substance Registration System (SRS) supports health information technology initiatives by generating unique ingredient identifiers for ingredients in FDA-regulated products. The FDA UNII is a nonproprietary, free, unique, nonsemantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information. For the purposes of the SRS system, substances that form noncovalent interactions with other added substances are not new substances or mixtures of substances; they are defined as separate substances.

Many ingredients already have FDA UNII. For ingredients that are not already in SRS, you can request an FDA UNII by submitting necessary information to tobacco-UNII@fda.hhs.gov. More information regarding SRS is posted at <http://www.fda.gov/forindustry/datastandards/substanceregistrationsystem-uniqueingredientidentifierunii/default.htm>.

b. Leaf Tobacco

Leaf tobacco (i.e., whole leaf or parts) that has been prepared solely by mechanical processing that involves no chemical, additive, or substance other than potable water is to be uniquely identified by providing the following information:

- the type (e.g., burley, bright, oriental)
- the variety
- the cure method (e.g., flue, fire, sun, steam, air) and heat source (e.g., propane, wood)
- a description of any recombinant DNA technology used to engineer the tobacco.

We consider the cure method and curing heat source necessary to uniquely identify tobacco-derived materials because these factors change the tobacco composition by altering endogenous constituents (e.g., sugars) and, in some circumstances, adding exogenous constituents (e.g., from partially pyrolyzed organic matter), thus resulting in a distinctly different tobacco material.

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329 Similarly, we believe that tobacco derived from recombinant DNA technology (e.g., tobacco
330 mosaic virus RNA vector) is intrinsically distinct from unmodified tobacco and that a description
331 of the modification and technology used is, therefore, necessary as part of the identification.
332

333 FDA requests that you further identify the leaf tobacco with any internal identification number
334 (e.g., SKU, product code) used within your company to reference the ingredient.
335

336 Tobacco that has been processed with any chemical, additive, or substance other than potable
337 water is to be reported as described in section III.D.3.c below. Each type of leaf tobacco used in
338 a tobacco product is to be reported as a separate ingredient. For example, if you purchase a
339 tobacco leaf blend or reconstituted tobacco for use in manufacturing a tobacco product, you are
340 to report the blend or reconstituted tobacco as described in section III.D.3.c below. The
341 manufacturer responsible for assembling the blend or reconstituting the tobacco is to submit
342 ingredient lists for its tobacco products and, in doing so, reporting each type of leaf tobacco used
343 in the blend as described in this section.
344

c. Complex Purchased Ingredients

345
346
347 Ingredients that are not single chemical substances or single types of leaf tobacco are considered
348 complex ingredients to be identified as described in this section. Such ingredients include, for
349 example, chocolate, flavor extracts, tobacco leaf blends, and reconstituted tobacco. Such
350 ingredients also include naturally derived, mechanically processed ingredients (e.g., ground
351 spice, fruit juice). Identifiers such as CAS numbers and FDA UNII are not sufficient to
352 uniquely identify most complex ingredients, as they are comprised of multiple substances.
353 This guidance divides the category of complex purchased ingredients into two groups — those
354 that are made to your specifications and those that are not.
355

356 Complex ingredients that are made to your specifications (i.e., not available as a commodity but
357 custom prepared for you), including such ingredients purchased via contract or other commercial
358 arrangements, are to be uniquely identified. For this, we believe it is necessary to provide:

- 359 • the complete name of the manufacturer;
- 360 • the uniquely identifying item name and/or number (e.g., catalog number or UPC) used by
361 the manufacturer; and
- 362 • information to uniquely identify each specified ingredient (i.e., each ingredient you
363 specified that the manufacturer use in manufacturing). Each specified ingredient is to be
364 uniquely identified in the same manner as used for other ingredients.

365 To further identify complex ingredients that are made to your specifications, FDA requests that
366 you provide the quality (e.g., percent purity, a published standard) of each specified ingredient,
367 the expected function(s) of each specified ingredient, any internal identification number (e.g.,
368 SKU, product code) used within your company to reference the complex ingredient, and any
369 additional specifications for the complex ingredient (e.g., release specifications, acceptance
370 criteria, a sample certificate of analysis).
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372 Complex ingredients that are not made to your specifications are also to be uniquely identified.
373 For this, we believe it is necessary to provide:

- 374
- the complete name of the manufacturer; and
 - the uniquely identifying item name and/or number (e.g., catalog number or UPC) used by the manufacturer. The uniquely identifying name and/or number for a complex ingredient that is available for purchase by the general public is one assigned by the seller, not one internally assigned by your company.
- 375
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379 To further identify complex ingredients not made to your specifications, FDA requests that you
380 provide the quality (e.g., percent purity, a published standard) of the complex ingredient, the
381 expected function(s) of the complex ingredient, and any internal identification number (e.g.,
382 SKU, product code) used within your company to reference the complex ingredient.

383 Many of the complex ingredients purchased for use in tobacco products are proprietary blends.
384 You do not need to list any substance contained in a complex purchased ingredient where the
385 ingredient is not made to your specifications. The manufacturer of the complex ingredient,
386 however, may be subject to ingredient listing reporting requirements, as described in section
387 III.B.

388
389 If you use a complex ingredient provided by multiple suppliers interchangeably in a single
390 tobacco product, you are to report all alternative sources in your ingredient listing, including
391 sufficient information to link the ingredients you consider interchangeable.

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d. Reaction Products

394 When the manufacturer knows or intends that an ingredient will be formed through a chemical
395 reaction during tobacco product manufacturing, FDA considers the resultant material to be an
396 ingredient that is added by the tobacco product manufacturer. As such, these reaction products
397 are to be included in the ingredient listing. Reaction products may result from, among other
398 things, reactions that occur during a mixing or processing operation (e.g., casing and drying),
399 during an in-process holding step, or during a storage period. The reaction product(s) may result
400 from a reaction between ingredients in the same part of a product (e.g., reconstituted tobacco) or
401 between ingredients added to different parts of the product (e.g., tobacco, paper) or added at
402 different manufacturing steps. Also, the reaction may occur between added ingredients or
403 between ingredients and chemicals intrinsic to the cured tobacco leaf.

404 Each reaction product ingredient is to be uniquely identified in the same manner used for single
405 chemical substances. To further identify these reaction products, FDA requests that you state
406 which added ingredients combined to form the reaction product and the expected function(s) of
407 the reaction product ingredient.

408

4. *Part to Which the Ingredient Is Added*

410

411 Section 904(a)(1) of the FD&C Act requires a listing of ingredients that are added by the
412 manufacturer to the tobacco, paper, filter, or other part. FDA interprets this to mean that

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413 manufacturers/importers are to specify whether an ingredient is added to the tobacco, to the
414 paper, to the filter, or to another part of the tobacco product.

415

416 5. *Ingredient Quantity*

417

418 Under section 904(a)(1) of the FD&C Act, you must report ingredients by quantity by brand and
419 subbrand. Under section 904(d) and (e), FDA is required to publish a list of harmful constituents
420 by quantity in each tobacco product by brand and subbrand. FDA intends to rely on consistent
421 reporting from manufacturers and importers to publish this list in a manner that is useful to the
422 public and not misleading to laypersons. Therefore, ingredient information is to be provided
423 using units that are consistent across all products. In addition, the reporting of ingredient
424 quantities is intended to provide the Agency with information to assist with implementation of
425 other provisions of the FD&C Act (e.g., developing tobacco product standards and making
426 substantial equivalence determinations). As such, the quantities need to be reported in consistent
427 units across all products using an absolute measurement that is conserved during chemical
428 reactions. FDA, therefore, interprets the term quantity to mean a unit of mass (i.e., grams with a
429 standard International System of Units prefix as appropriate) of an ingredient contained in a
430 tobacco product.

431

432 For all tobacco products, quantity is to be expressed in terms of the unit of use for a portioned
433 tobacco product (e.g., one cigarette, one cigar) or per gram of product for a nonportioned tobacco
434 product (e.g., container of loose snuff, reconstituted tobacco, hookah tobacco, hookah charcoal,
435 e-liquids).

436

437 Solvents or other ingredients that are added and subsequently removed during manufacturing are
438 still considered to be added ingredients under section 904(a)(1) of the FD&C Act. As such, the
439 removed ingredient is to be identified and the residual quantity stated (with an appropriate
440 detection limit if the quantity is approximated near zero).

441

442 You are to report all ingredient quantities contained in the tobacco product. You may calculate
443 the quantity based on the added amounts and adjusting for known or intended losses and
444 chemical reactions during manufacturing. Alternatively, the quantity contained in the tobacco
445 product may be derived from laboratory testing.

446

447 You are to report ingredients as a single quantity whenever possible. FDA understands,
448 however, that in some circumstances manufacturers add ingredients based upon manufacturing
449 specifications to affect product characteristics (e.g., to adjust for total sugars or to achieve a
450 particular pH) resulting in the manufacturer adding varying amounts from batch to batch. If you
451 add a particular ingredient in this way, you are to give the quantity by providing both the range
452 of permitted quantities (e.g., add between 1.01 and 1.05 mg to the product) and the targeted
453 outcome (e.g., in order to achieve a pH of 7.1). Both the range of permitted quantities and the
454 targeted outcome are to be derived from the manufacturing specifications for the addition of the
455 ingredient. Where no quantity range is contained in, or can be derived from, manufacturing
456 specifications, it is to be derived from the actual range of historical quantities added to the
457 product.

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458
459 Section 904(c) requires the submission of information whenever the quantity of an additive is
460 changed. Almost all ingredients are additives, as that term is defined in section III.A. The
461 quantity before and after the change are reported. A change to the manufacturing specifications
462 for the addition of an additive or to the quantity of an additive as reported constitutes a change
463 triggering the reporting requirements in section 904(c).

E. How Do You Submit Ingredient Information?

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465
466
467 FDA strongly encourages you to make your submission electronically. An electronic submission
468 reduces paper and facilitates efficient (and timely) submissions to the Agency and efficient
469 processing, review, and archiving of the submission once at FDA.

470
471 The FDA eSubmitter tool (eSubmitter) is software provided by FDA for the preparation of
472 electronic submissions. This tool provides a template form to report ingredient data and an
473 automatic acknowledgement of FDA receipt and allows users to attach large numbers of files,
474 such as PDF documents.

475
476 To use eSubmitter, first download the tool from the FDA Web site at
477 <http://www.fda.gov/ForIndustry/FDAeSubmitter> and install it on your computer.¹² Select the
478 “CTP Tobacco Product Ingredient Listing Submissions” within the eSubmitter program and
479 enter information about your ingredient listing directly into the software. You will not need to
480 prepare additional documents with this information, and you will not need to complete form
481 FDA 3742.

482
483 You can then use eSubmitter to enter data, attach files, and upload the completed submission
484 through the CTP Portal or FDA Electronic Submissions Gateway (ESG). You will need to apply
485 for a free account to upload data through either the CTP Portal
486 (<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm>) or ESG. Due to the time needed to create new accounts, FDA urges
487 submitters to apply for accounts several weeks in advance of when you intend to submit.
488

489
490 The FDA eSubmitter tool can also streamline the process for submitting updated ingredient
491 listing information required by section 904(c).

492
493 Although FDA strongly encourages electronic submission, FDA Form 3742, an alternative tool
494 for paper submissions, is available at
495 <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/Tobacco/default.htm>
496 Paper submissions may be mailed to:
497

¹² The eSubmitter tool requires a computer that runs MS Windows.

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498 Food and Drug Administration
499 Center for Tobacco Products
500 Document Control Center
501 Building 71, Room G335
502 10903 New Hampshire Avenue
503 Silver Spring, MD 20993-0002
504

505 Submissions delivered to DCC by couriers or physical mail will be considered timely if received
506 during delivery hours on or before the due date (see
507 <http://www.fda.gov/tobaccoproducts/aboutctp/contactus/default.htm>); if the due date falls on a
508 weekend or holiday, the delivery must be received on the prior business day. We are unable to
509 accept regulatory submissions by e-mail.
510

F. When Do You Submit Ingredient Information?

511
512
513 Manufacturers and importers of cigarettes, cigarette tobacco, RYO, and smokeless tobacco
514 products that were introduced into interstate commerce before June 22, 2009, were required by
515 section 904(a)(1) of the FD&C Act to submit a list of all ingredients by December 22, 2009.¹³
516 For cigarettes, cigarette tobacco, RYO, and smokeless tobacco products that were first marketed
517 after June 22, 2009, ingredient lists are due at least 90 days before the product is delivered for
518 introduction into interstate commerce (section 904(c)(1)). Section 904(c) also requires
519 submission of information whenever any additive, or the quantity of any additive, is changed.
520 Submissions under section 904(a)(1) consist of a listing of all ingredients added as of the date of
521 submission.
522

523 The preamble to the deeming rule (81 FR 28974) stated that FDA does not intend to enforce the
524 requirement to submit ingredient listing for manufacturers and importers of newly deemed
525 tobacco products that were introduced into interstate commerce on or before August 8, 2016
526 provided submissions are received by February 8, 2017, or August 8, 2017 for small-scale
527 manufacturers. However, FDA recognizes that some manufacturers of newly deemed products
528 are not familiar with the forms for listing ingredients and, therefore, may need additional time to
529 complete them accurately. In addition, we are aware that some manufacturers may need to
530 prepare and submit multiple lists. Therefore, at this time, for manufacturers and importers of
531 newly deemed tobacco products (21 CFR part 1100) that were introduced into interstate
532 commerce on or before August 8, 2016, FDA does not intend to enforce the requirement to
533 submit ingredient information according to section 904(a)(1) until November 8, 2017. For
534 small-scale manufacturers of newly deemed tobacco products (21 CFR part 1100) that were
535 introduced into interstate commerce on or before August 8, 2016, FDA does not intend to
536 enforce the requirement to submit ingredient information according to section 904(a)(1) until
537 May 8, 2018. FDA believes that this additional time will allow manufacturers to prepare higher

¹³ FDA did not enforce the December 22, 2009 deadline in situations where the ingredient list was submitted on or before June 22, 2010, pursuant to a compliancy policy described in the November 2009 edition of this guidance.

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538 quality submissions. However, because we may receive a large number of submissions from
539 certain firms, we encourage manufacturers to begin the process as early as possible.

540 Additionally, FDA is extending the compliance deadlines with respect to products on the market
541 as of August 8, 2016, by an additional six months for tobacco product manufacturers and
542 importers in the areas impacted by recent natural disasters to May 8, 2018, and to November 8,
543 2018, for small-scale manufacturers impacted by recent natural disasters.¹⁴

544 Tobacco products introduced into interstate commerce after August 8, 2016, are required to
545 submit the ingredient information required by section 904(a)(1) at least 90 days before the
546 product is introduced to interstate commerce.

547
548 You are not required to submit ingredient lists for tobacco products that you discontinued and
549 stopped manufacturing before the date of your submission under section 904(a)(1). Such
550 discontinued products, if manufactured and reintroduced into the market, will, however, require
551 the ingredient submission under section 904(c)(1). Under that section, you are to submit the
552 product ingredient list at least 90 days prior to delivery for introduction into interstate commerce.
553 When a tobacco product manufacturer makes a change to the additives in its cigarettes, cigarette
554 tobacco, RYO, and smokeless tobacco products after June 22, 2009, sections 904(c)(2) and (c)(3)
555 require the manufacturer to report these changes. After August 8, 2016, FDA intends to enforce
556 sections 904(c)(2) and (c)(3) for changes in additives to all tobacco products except for
557 accessories of newly deemed products.

558
559 Specifically, under sections 904(c)(2) and (c)(3), if a manufacturer:

- 560 • eliminates or decreases an existing additive, the change must be reported to FDA within 60
561 days of making the change;
- 562 • adds or increases an additive that FDA has designated in regulations as a tobacco additive
563 that is not a human or animal carcinogen and is not otherwise harmful to health under the
564 intended conditions of use, the change must be reported to FDA within 60 days of making
565 the change; or
- 566 • adds a new tobacco additive or increases the quantity of an existing tobacco additive (not
567 designated as described above), the change must be reported to FDA at least 90 days prior to
568 making the change.

569

570 **FDA COMPLIANCE POLICY FOR INGREDIENT LIST SUBMISSIONS**

¹⁴ For a complete list of the areas that have been impacted by recent natural disasters, please visit
<https://www.fda.gov/TobaccoProducts/NewsEvents/ucm579265.htm>.

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| | FDA Intends to Enforce Ingredient Submissions for These Products | Date of Introduction or Reintroduction | Submission Type | Date to Submit |
|--|---|--|------------------------|--|
| Cigarettes, cigarette tobacco, RYO, and smokeless tobacco | <ul style="list-style-type: none"> Finished tobacco products | Products on the market continuously since June 22, 2009, or earlier. | section 904(a)(1) | FDA did not begin enforcing until June 22, 2010 |
| | | Previously marketed products that were discontinued or withdrawn before June 22, 2009, and reintroduced after June 22, 2009. | section 904(c)(1) | 90 days prior to delivery for reintroduction into interstate commerce |
| | | Products marketed for the first time after June 22, 2009 | section 904(c)(1) | 90 days prior to delivery for introduction into interstate commerce |
| Tobacco products <i>other than</i> cigarettes, cigarette tobacco, RYO, and smokeless tobacco | <ul style="list-style-type: none"> Finished tobacco products | Products on the market as of August 8, 2016 | section 904(a)(1) | <ul style="list-style-type: none"> FDA does not intend to enforce until November 8, 2017, for other manufacturers (or May 8, 2018, for manufacturers in areas impacted by recent natural disasters)¹⁵ FDA does not intend to enforce until May 8, 2018, for small scale manufacturers (or November 8, 2018, for small-scale manufacturers in areas impacted by recent natural disasters)¹⁶ |
| | | Previously marketed products that were discontinued or withdrawn before August 8, 2016, and reintroduced after | section 904(c)(1) | 90 days prior to delivery for reintroduction into interstate commerce |

¹⁵ For a complete list of the areas that have been impacted by recent natural disasters, please visit <https://www.fda.gov/TobaccoProducts/NewsEvents/ucm579265.htm>.

¹⁶ For a complete list of the areas that have been impacted by recent natural disasters, please visit <https://www.fda.gov/TobaccoProducts/NewsEvents/ucm579265.htm>.

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| | FDA Intends to Enforce Ingredient Submissions for These Products | Date of Introduction or Reintroduction | Submission Type | Date to Submit |
|--|--|---|-------------------|---|
| | | August 8, 2016 | | |
| | | Products marketed for the first time after August 8, 2016 | section 904(c)(1) | 90 days prior to delivery for introduction into interstate commerce |

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G. Will FDA Maintain the Confidentiality of the Ingredient Information You Submit?

Information submitted under section 904 of the FD&C Act may include, but is not limited to, a company's nonpublic trade secret or confidential commercial information.

Several laws govern the confidentiality of ingredient information submitted under section 904 of the FD&C Act, including sections 301(j) and 906(c) of the FD&C Act (21 U.S.C. 331(j) and 387f(c)), the Trade Secrets Act (18 U.S.C. 1905), and the Freedom of Information Act (FOIA) (5 U.S.C. 552), as well as FDA's implementing regulations.

Section 906(c) of the FD&C Act prohibits FDA from disclosing any information reported to or otherwise obtained by FDA under section 904, among other provisions, if that information is confidential commercial or trade secret information exempt from disclosure under FOIA Exemption 4 (5 U.S.C. 552(b)(4)). The provision contains exceptions allowing disclosure of the information to other officers or employees concerned with carrying out the tobacco products chapter of the FD&C Act and, when relevant, in any proceeding under the tobacco products chapter of the FD&C Act. Section 301(j) of the FD&C Act generally prohibits release of trade secret information obtained by FDA under section 904, among other provisions, outside of the Department of Health and Human Services, except to courts when relevant in any judicial proceeding under the FD&C Act and to Congress in response to an authorized Congressional request.

FDA's general regulations concerning the public availability of FDA records are contained in 21 CFR part 20.

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598 **V. PAPERWORK REDUCTION ACT OF 1995**

599 This guidance contains information collection provisions that are subject to review by the Office
600 of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C.
601 3501-3520).

602 The time required to complete this information collection is estimated to average 3.75 hours per
603 response, including the time to review instructions, search existing data sources, gather the data
604 needed, and complete and review the information collection. Send comments regarding this
605 burden estimate or suggestions for reducing this burden to:

606 Food and Drug Administration
607 Center for Tobacco Products
608 Document Control Center
609 Building 71, Room G335
610 10903 New Hampshire Avenue
611 Silver Spring, MD 20993-0002

612 An Agency may not conduct or sponsor, and a person is not required to respond to, a collection
613 of information unless it displays a currently valid OMB control number. The OMB control
614 number for this information collection is 0910-0650 (expires 6/30/2019).

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617 DOCUMENT HISTORY

618 **November 2009** — First edition of guidance issued.

619 **January 2017** — *Listing of Ingredients in Tobacco Products* guidance revised to reflect changes
620 in FDA authorities over “deemed” tobacco products. Revisions include minor clarifying and
621 editorial changes to promote consistency throughout our guidances, incorporate “plain
622 language,” and employ grammatically correct phrasing. Specific revisions include the following:

- 623 • Section II — Background updated to reflect changes in FDA authorities over “deemed”
624 tobacco products arising from deeming rule.
625
- 626 • Section III — Definitions of *accessory*, *component* or *part*, *small-scale tobacco product*
627 *manufacturer*, and *finished tobacco product* added; definition of *importer* and *pouch*
628 updated.
629
- 630 • Section III.B — Section B “Who Submits Ingredient Listing?” compliance policy for
631 cigarettes, cigarette tobacco, RYO, and smokeless tobacco deleted.
632
- 633 • Section III.C — “FDA’s Compliance Policy for Regulated Tobacco Products” added.
634
- 635 • Former section III.C — “What Information Is Submitted With the List of Ingredients?”
636 becomes section III.D.
637
- 638 • Section III.D — Information on Data Universal Numbering System is updated.
639
- 640 • Former section III.D — “How Do You Submit Ingredient Information?” becomes section
641 III.E.
642
- 643 • Section III.E — Information on how to submit ingredient listing information updated.
644
- 645 • Former section III.E — “When Do You Submit Ingredient Listing Information?”
646 becomes section III.F.
647
- 648 • Section III.F — Updated to include submission dates for newly deemed products and
649 provide compliance policy explaining that for tobacco products that were manufactured
650 prior to August 8, 2016, FDA does not intend to enforce the requirement to provide
651 ingredient listing until August 8, 2017, or February 8, 2018, for small-scale
652 manufacturers.
653
- 654 • Former section III.F — “Will the FDA Maintain the Confidentiality of the Ingredient
655 Information You Submit?” becomes section III.G.
656
- 657 • PRA section updated
658

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659 **October 2017** — Revised compliance dates (1) to reflect compliance dates in the “Extension of
660 Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule” guidance
661 issued in August 2017 and (2) to provide a six-month extension for tobacco product
662 manufacturers and importers in areas impacted by recent natural disasters.