

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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* This is the fourth 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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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;

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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- 29 • How to submit the information;
- 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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39 **II. BACKGROUND**

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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

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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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,
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 May 8, 2018, for businesses that are not
79 small-scale manufacturers, and November 8, 2018, for small-scale manufacturers (81 FR 28974
80 at 29008).⁶

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

86 The failure to provide any information required by section 904 is a prohibited act under section
87 301(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 These compliance dates apply to all firms regardless of whether the manufacturer or importer is in an area impacted by recent natural disasters, as described in the October 2017 edition of this guidance.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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88 903(a)(10)(A) of the FD&C Act (21 U.S.C. 387c(a)(10)(A)), a tobacco product is deemed
89 misbranded if there was any failure or refusal to comply with any requirement prescribed under
90 section 904. Violations relating to section 904 are subject to regulatory and enforcement action
91 by FDA, including, but not limited to, seizure and injunction.

92

93 **III. DISCUSSION**

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

96

97 FDA intends to use the following definitions to implement the ingredient listing requirements of
98 section 904 of the FD&C Act:

99

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

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

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

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

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

110

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

118

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

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

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

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

125 FDA notes that *component* and *part* are separate and distinct terms within chapter IX of the
126 FD&C Act. However, for purposes of this guidance, FDA is using the terms *component* and
127 *part* interchangeably and without emphasizing the distinction. FDA may clarify the
128 distinctions between *component* and *part* in the future.

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- 130 • ***Finished tobacco product:*** The term *finished tobacco product* means a tobacco product,
131 including all components and parts, sealed in final packaging intended for consumer use
132 (e.g., filters or filter tubes sold separately to consumers or as part of kits).
133
- 134 • ***Importer:*** The term *importer* means any person who imports any tobacco product that is
135 intended for sale or distribution to consumers in the United States.
136
- 137 • ***Pouch:*** The term *pouch* means a permeable material, intended to be filled with pre-
138 portioned tobacco product and placed in the oral cavity with the tobacco product.
139
- 140 • ***Small-scale tobacco product manufacturer:*** The term *small-scale tobacco product*
141 *manufacturer* means a manufacturer of any regulated tobacco product that employs 150 or
142 fewer full-time equivalent employees and has annual total revenues of \$5 million or less.
143 FDA considers a manufacturer to include each entity that it controls, is controlled by, or is
144 under common control with.
145
- 146 • ***Tobacco product:*** The term *tobacco product* is defined in section 201(rr) of the FD&C Act,
147 which states in relevant part:
- 148 (1) The term “tobacco product” means any product made or derived from tobacco
149 that is intended for human consumption, including any component, part, or
150 accessory of a tobacco product (except for raw materials other than tobacco
151 used in manufacturing a component, part, or accessory of a tobacco product).”
152 (section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)).
- 153 (2) The term “tobacco product” does not include an article that is a drug under
154 [section 201(g)(1)], a device under [section 201(h)], or a combination product
155 [described in section 503(g) [of the FD&C Act (21 U.S.C. 353(g))].
- 156 Note that this definition includes accessories and components and parts of tobacco products,
157 whether they are made or derived from tobacco, and whether they are sold or distributed as
158 finished tobacco products.⁷
159
- 160 • ***Tobacco Product Manufacturer:*** The term *tobacco product manufacturer* means “any
161 person, including any repacker or relabeler, who (A) manufactures, fabricates, assembles,
162 processes, or labels a tobacco product; or (B) imports a finished tobacco product for sale
163 or distribution in the United States” (section 900(20) of the FD&C Act (21 U.S.C.
164 387(20)). Thus, the term is not limited to persons who manufacture products containing
165 tobacco, but includes anyone who manufactures any tobacco product as defined above.
166

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?

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

174
175 For tobacco products that are imported, the foreign manufacturer and the importer or importers
176 of an imported product will need to work together to ensure that the ingredient information is
177 submitted to FDA as required by section 904. If there is a failure or refusal to comply with the
178 ingredient listing requirements, then — among other things — the product is deemed misbranded
179 under section 903(a)(10)(A) and therefore subject to refusal of admission into the United States.

180
181 Submissions under section 904(c) are required to be made by the tobacco product manufacturer.
182 An importer of a finished tobacco product for sale or distribution in the United States falls within
183 the definition of a *manufacturer*. An importer that is not a manufacturer required to submit
184 information or reports under section 904(c) may, however, submit the information as an agent on
185 behalf of the manufacturer.

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

186
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188
189 At this time, with respect to all tobacco products, including cigarettes, cigarette tobacco, RYO,
190 smokeless tobacco, as well as other tobacco products now regulated as a result of the deeming
191 rule, FDA intends to enforce the ingredients submission requirements of section 904(a)(1) with
192 respect to finished tobacco products only. FDA does not, at this time, intend to enforce these
193 requirements with respect to products that are sold or distributed solely for further
194 manufacturing.

195
196 As defined above, the term *finished tobacco product* means a tobacco product, including all
197 components and parts, sealed in final packaging intended for consumer use (e.g., filters or filter
198 tubes sold separately to consumers or as part of kits).

199
200 Components and parts that are sold separately from other tobacco products are also finished
201 tobacco products if they are sold in final packaging intended for consumer use. FDA intends to
202 enforce the requirements for submission of ingredient information under section 904(a)(1) with
203 respect to such products. Examples of components and parts that are sold or may be sold as
204 finished tobacco products include pipe tobacco filler, filter tubes, e-cigarette batteries, and e-
205 liquids, whether sold separately to consumers or as part of kits.

206
207 Based on our experience with cigarettes, cigarette tobacco, RYO and smokeless tobacco, we are
208 amending our previous compliance policy. Under our previous policy, FDA intended to enforce
209 the submission of the listing of ingredients requirements with respect to owners and operators
210 engaged in the manufacture of tobacco, papers, filters, and pouches whether or not such products
211 are for further manufacturing of, or for consumer use as, regulated tobacco products. However,

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

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

1. Manufacturer/Importer Identification

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

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

2. Product Identification

236 Under section 904(a)(1) of the FD&C Act, tobacco product manufacturers or importers are
237 required to submit ingredient lists for “each tobacco product by brand and by quantity in each
238
239

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

249
250 For each ingredient list, clearly and uniquely identify the product by brand and subbrand,
251 including the type or category of tobacco product (e.g., cigarette, smokeless tobacco product,
252 cigar, ENDS, waterpipe tobacco product) and subcategory.¹¹ You are to include additional
253 identifiers (e.g., stock-keeping units (SKUs), Universal Product Codes (UPCs), and catalog
254 numbers) as needed to uniquely identify the brand and subbrand of the product.

255 256 3. *Ingredient Identification*

257
258 Section 904(a)(1) of the FD&C Act sets forth the requirements for submission of ingredient
259 information. The statute requires a listing of all ingredients, including tobacco, substances,
260 compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or
261 other part of each tobacco product as of the date of submission. Ingredients must be specified for
262 each brand and subbrand of tobacco product.

263
264 FDA considers all ingredients added directly by, or at the direction of, the tobacco product
265 manufacturer to be added by the manufacturer. When the manufacturer knows or intends that an
266 ingredient is formed through a chemical reaction during tobacco product manufacturing, FDA
267 considers the resultant material to be an ingredient that is added by the manufacturer. Similarly,
268 when the manufacturer knows or intends that an ingredient added to any type of packaging will
269 become incorporated into the consumed product, that ingredient is considered to be added by the
270 manufacturer to the tobacco product.

271
272 Each listed ingredient is to be uniquely identified so as to distinguish it from similar or related
273 materials. The information necessary to uniquely identify an ingredient varies based upon the
274 type of ingredient as discussed below. For single chemical substances and complex purchased
275 ingredients, FDA also requests that you provide additional information, including the expected
276 functions of each ingredient. By asking for the functions of the ingredient, the agency requests
277 that you identify all expected functions of the ingredient in the final product. As examples, an
278 ingredient may function as a humectant, flavor, or chemo-sensory agent that affects perception of
279 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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325 Similarly, we believe that tobacco derived from recombinant DNA technology (e.g., tobacco
326 mosaic virus RNA vector) is intrinsically distinct from unmodified tobacco and that a description
327 of the modification and technology used is, therefore, necessary as part of the identification.
328

329 FDA requests that you further identify the leaf tobacco with any internal identification number
330 (e.g., SKU, product code) used within your company to reference the ingredient.
331

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

c. Complex Purchased Ingredients

341
342 Ingredients that are not single chemical substances or single types of leaf tobacco are considered
343 complex ingredients to be identified as described in this section. Such ingredients include, for
344 example, chocolate, flavor extracts, tobacco leaf blends, and reconstituted tobacco. Such
345 ingredients also include naturally derived, mechanically processed ingredients (e.g., ground
346 spice, fruit juice). Identifiers such as CAS numbers and FDA UNIIs are not sufficient to
347 uniquely identify most complex ingredients, as they are comprised of multiple substances.
348 This guidance divides the category of complex purchased ingredients into two groups — those
349 that are made to your specifications and those that are not.
350
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352 Complex ingredients that are made to your specifications (i.e., not available as a commodity but
353 custom prepared for you), including such ingredients purchased via contract or other commercial
354 arrangements, are to be uniquely identified. For this, we believe it is necessary to provide:

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

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

- 370 • the complete name of the manufacturer; and
- 371 • the uniquely identifying item name and/or number (e.g., catalog number or UPC) used by
372 the manufacturer. The uniquely identifying name and/or number for a complex ingredient
373 that is available for purchase by the general public is one assigned by the seller, not one
374 internally assigned by your company.

375 To further identify complex ingredients not made to your specifications, FDA requests that you
376 provide the quality (e.g., percent purity, a published standard) of the complex ingredient, the
377 expected function(s) of the complex ingredient, and any internal identification number (e.g.,
378 SKU, product code) used within your company to reference the complex ingredient.

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

384

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

388

389 d. Reaction Products

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

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

404

405 4. *Part to Which the Ingredient Is Added*

406

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

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

411

412 5. *Ingredient Quantity*

413

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

427

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

432

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

437

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

442

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

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454
455 Section 904(c) requires the submission of information whenever the quantity of an additive is
456 changed. Almost all ingredients are additives, as that term is defined in section III.A. The
457 quantity before and after the change are reported. A change to the manufacturing specifications
458 for the addition of an additive or to the quantity of an additive as reported constitutes a change
459 triggering the reporting requirements in section 904(c).
460

E. How Do You Submit Ingredient Information?

461
462
463 FDA strongly encourages you to make your submission electronically. An electronic submission
464 reduces paper and facilitates efficient (and timely) submissions to the Agency and efficient
465 processing, review, and archiving of the submission once at FDA.
466

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

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

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

486 The FDA eSubmitter tool can also streamline the process for submitting updated ingredient
487 listing information required by section 904(c).
488

489 Although FDA strongly encourages electronic submission, FDA Form 3742, an alternative tool
490 for paper submissions, is available at

491 <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/Tobacco/default.htm>

492 Paper submissions may be mailed to:
493

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

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494 Food and Drug Administration
495 Center for Tobacco Products
496 Document Control Center
497 Building 71, Room G335
498 10903 New Hampshire Avenue
499 Silver Spring, MD 20993-0002
500

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

F. When Do You Submit Ingredient Information?

507
508
509 Manufacturers and importers of cigarettes, cigarette tobacco, RYO, and smokeless tobacco
510 products that were introduced into interstate commerce before June 22, 2009, were required by
511 section 904(a)(1) of the FD&C Act to submit a list of all ingredients by December 22, 2009.¹³
512 For cigarettes, cigarette tobacco, RYO, and smokeless tobacco products that were first marketed
513 after June 22, 2009, ingredient lists are due at least 90 days before the product is delivered for
514 introduction into interstate commerce (section 904(c)(1)). Section 904(c) also requires
515 submission of information whenever any additive, or the quantity of any additive, is changed.
516 Submissions under section 904(a)(1) consist of a listing of all ingredients added as of the date of
517 submission.
518

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

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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534 submissions. However, because we may receive a large number of submissions from certain
535 firms, we encourage manufacturers to begin the process as early as possible.¹⁴

536

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

540

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

551

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

553 • eliminates or decreases an existing additive, the change must be reported to FDA within 60
554 days of making the change;

555 • adds or increases an additive that FDA has designated in regulations as a tobacco additive
556 that is not a human or animal carcinogen and is not otherwise harmful to health under the
557 intended conditions of use, the change must be reported to FDA within 60 days of making
558 the change; or

559 • adds a new tobacco additive or increases the quantity of an existing tobacco additive (not
560 designated as described above), the change must be reported to FDA at least 90 days prior to
561 making the change.

562

563

FDA COMPLIANCE POLICY FOR INGREDIENT LIST SUBMISSIONS

¹⁴ These compliance dates apply to all firms regardless of whether the manufacturer or importer is in an area impacted by recent natural disasters, as described in the October 2017 edition of this guidance.¹⁵ This compliance date applies to all firms regardless of whether the manufacturer or importer is in an area impacted by recent natural disasters, as described in the October 2017 edition of this guidance.

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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 May 8, 2018¹⁵ FDA does not intend to enforce until November 8, 2018, for small scale manufacturers¹⁶
		Previously marketed products that were discontinued or withdrawn before August 8, 2016, and reintroduced after August 8, 2016	section 904(c)(1)	90 days prior to delivery for reintroduction into interstate commerce
		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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566
567

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

¹⁵ This compliance date applies to all firms regardless of whether the manufacturer or importer is in an area impacted by recent natural disasters, as described in the October 2017 edition of this guidance.

¹⁶ This compliance date applies to all firms regardless of whether the manufacturer or importer is in an area impacted by recent natural disasters, as described in the October 2017 edition of this guidance.

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

570
571 Several laws govern the confidentiality of ingredient information submitted under section 904 of
572 the FD&C Act, including sections 301(j) and 906(c) of the FD&C Act (21 U.S.C. 331(j) and
573 387f(c)), the Trade Secrets Act (18 U.S.C. 1905), and the Freedom of Information Act (FOIA) (5
574 U.S.C. 552), as well as FDA's implementing regulations.

575
576 Section 906(c) of the FD&C Act prohibits FDA from disclosing any information reported to or
577 otherwise obtained by FDA under section 904, among other provisions, if that information is
578 confidential commercial or trade secret information exempt from disclosure under FOIA
579 Exemption 4 (5 U.S.C. 552(b)(4)). The provision contains exceptions allowing disclosure of the
580 information to other officers or employees concerned with carrying out the tobacco products
581 chapter of the FD&C Act and, when relevant, in any proceeding under the tobacco products
582 chapter of the FD&C Act. Section 301(j) of the FD&C Act generally prohibits release of trade
583 secret information obtained by FDA under section 904, among other provisions, outside of the
584 Department of Health and Human Services, except to courts when relevant in any judicial
585 proceeding under the FD&C Act and to Congress in response to an authorized Congressional
586 request.

587
588 FDA's general regulations concerning the public availability of FDA records are contained in 21
589 CFR part 20.

590

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

592 This guidance contains information collection provisions that are subject to review by the Office
593 of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C.
594 3501-3520).

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

599 Food and Drug Administration
600 Center for Tobacco Products
601 Document Control Center
602 Building 71, Room G335
603 10903 New Hampshire Avenue
604 Silver Spring, MD 20993-0002

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

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610 **DOCUMENT HISTORY**

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

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

- 616 • Section II — Background updated to reflect changes in FDA authorities over “deemed”
617 tobacco products arising from deeming rule.
618
- 619 • Section III — Definitions of *accessory, component or part, small-scale tobacco product*
620 *manufacturer, and finished tobacco product* added; definition of *importer* and *pouch*
621 updated.
622
- 623 • Section III.B — Section B “Who Submits Ingredient Listing?” compliance policy for
624 cigarettes, cigarette tobacco, RYO, and smokeless tobacco deleted.
625
- 626 • Section III.C — “FDA’s Compliance Policy for Regulated Tobacco Products” added.
627
- 628 • Former section III.C — “What Information Is Submitted With the List of Ingredients?”
629 becomes section III.D.
630
- 631 • Section III.D — Information on Data Universal Numbering System is updated.
632
- 633 • Former section III.D — “How Do You Submit Ingredient Information?” becomes section
634 III.E.
635
- 636 • Section III.E — Information on how to submit ingredient listing information updated.
637
- 638 • Former section III.E — “When Do You Submit Ingredient Listing Information?”
639 becomes section III.F.
640
- 641 • Section III.F — Updated to include submission dates for newly deemed products and
642 provide compliance policy explaining that for tobacco products that were manufactured
643 prior to August 8, 2016, FDA does not intend to enforce the requirement to provide
644 ingredient listing until August 8, 2017, or February 8, 2018, for small-scale
645 manufacturers.
646
- 647 • Former section III.F — “Will the FDA Maintain the Confidentiality of the Ingredient
648 Information You Submit?” becomes section III.G.
649
- 650 • PRA section updated
651

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

656 **November 2017** --- Revised compliance dates to provide a six-month extension for all tobacco
657 product manufacturers and importers, regardless of whether the manufacturer or importer is in an
658 area impacted by recent natural disasters, as described in the October 2017 edition of this
659 guidance.