

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 <https://www.regulations.gov>. Alternatively, submit written comments to the Dockets Management Staff (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.

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* This is the sixth 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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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

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
- 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.

37
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

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. 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 The failure to provide any information required by section 904 is a prohibited act under section
73 301(q)(1)(B) of the FD&C Act (21 U.S.C. 331(q)(1)(B)). In addition, under section
74 903(a)(10)(A) of the FD&C Act (21 U.S.C. 387c(a)(10)(A)), a tobacco product is deemed
75 misbranded if there was any failure or refusal to comply with any requirement prescribed under
76 section 904. Violations relating to section 904 are subject to regulatory and enforcement action
77 by FDA, including, but not limited to, seizure and injunction.

78 79 **III. DISCUSSION**

80 81 **A. What Definitions Apply to This Guidance?**

82
83 For the purposes of this guidance, FDA intends to use the following definitions:

- 84
- 85 • **Accessory:** The term *accessory* means any product that is intended or reasonably expected to
86 be used with or for the human consumption of a tobacco product; does not contain tobacco
87 and is not made or derived from tobacco; and meets either of the following:
88 (1) Is not intended or reasonably expected to affect or alter the performance, composition,
89 constituents, or characteristics of a tobacco product; or
90 (2) Is intended or reasonably expected to affect or maintain the performance, composition,
91 constituents, or characteristics of a tobacco product but
92 (i) Solely controls moisture and/or temperature of a stored tobacco product; or
93 (ii) Solely provides an external heat source to initiate but not maintain combustion of a
94 tobacco product.
95
 - 96 • **Additive:** The term *additive* means any substance the intended use of which results or
97 may reasonably be expected to result, directly or indirectly, in its becoming a component
98 or otherwise affecting the characteristic of any tobacco product (including any substances
99 intended for use as a flavoring or coloring or in producing, manufacturing, packing,
100 processing, preparing, treating, packaging, transporting, or holding), except that such
101 term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a
102 pesticide chemical. (section 900(1) of the FD&C Act (21 U.S.C. 387(1))
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- 104 • **Component or part:** The term *component* or *part* means any software or assembly of
105 materials intended or reasonably expected:
- 106 (1) To alter or affect the tobacco product’s performance, composition, constituents, or
107 characteristics; or
- 108 (2) To be used with or for the human consumption of a tobacco product.
- 109 Component or part excludes anything that is an accessory of a tobacco product.
- 110 FDA notes that *component* and *part* are separate and distinct terms within chapter IX of the
111 FD&C Act. However, for purposes of this guidance, FDA is using the terms *component* and
112 *part* interchangeably and without emphasizing the distinction. FDA may clarify the
113 distinctions between *component* and *part* in the future.
- 114
- 115 • **Finished tobacco product:** The term *finished tobacco product* means a tobacco product,
116 including all components and parts, sealed in final packaging intended for consumer use
117 (e.g., filters or filter tubes sold separately to consumers or as part of kits).
- 118
- 119 • **Importer:** The term *importer* means any person who imports any tobacco product that is
120 intended for sale or distribution to consumers in the United States.
- 121
- 122 • **Per weight composition:** The term *per weight composition* means the manner in which
123 the materials (e.g., ingredients, additives, and biological organisms) are arranged and
124 integrated to produce a finished tobacco product.
- 125
- 126 • **Pouch:** The term *pouch* means a permeable material, intended to be filled with pre-
127 portioned tobacco product and placed in the oral cavity with the tobacco product.
- 128
- 129 • **Small-scale tobacco product manufacturer:** The term *small-scale tobacco product*
130 *manufacturer* means a manufacturer of any regulated tobacco product that employs 150 or
131 fewer full-time equivalent employees and has annual total revenues of \$5 million or less.
132 FDA considers a manufacturer to include each entity that it controls, is controlled by, or is
133 under common control with.
- 134
- 135 • **Tobacco product:** The term *tobacco product* is defined in section 201(rr) of the FD&C Act,
136 which states in relevant part:
- 137 (1) The term “tobacco product” means any product made or derived from tobacco
138 that is intended for human consumption, including any component, part, or
139 accessory of a tobacco product (except for raw materials other than tobacco
140 used in manufacturing a component, part, or accessory of a tobacco product).”
141 (section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)).
- 142 (2) The term “tobacco product” does not include an article that is a drug under
143 [section 201(g)(1)], a device under [section 201(h)], or a combination product
144 [described in section 503(g) [of the FD&C Act (21 U.S.C. 353(g))].

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145 Note that this definition includes accessories and components and parts of tobacco products,
146 whether they are made or derived from tobacco, and whether they are sold or distributed as
147 finished tobacco products.⁴

- 148
- 149 • ***Tobacco Product Manufacturer:*** The term *tobacco product manufacturer* means “any
150 person, including any repacker or relabeler, who (A) manufactures, fabricates, assembles,
151 processes, or labels a tobacco product; or (B) imports a finished tobacco product for sale
152 or distribution in the United States” (section 900(20) of the FD&C Act (21 U.S.C.
153 387(20)). Thus, the term is not limited to persons who manufacture products containing
154 tobacco, but includes anyone who manufactures any tobacco product as defined above.
155

B. Who Submits Ingredient Information?

156

157

158 The requirements under section 904(a)(1) apply to each “tobacco product manufacturer or
159 importer.” We interpret this to mean that domestic manufacturers are to submit the required
160 ingredient information for products they manufacture and that either the foreign manufacturer or
161 the importer of the tobacco product is to submit the required ingredient information for imported
162 tobacco products.
163

164 For tobacco products that are imported, the foreign manufacturer and the importer or importers
165 of an imported product will need to work together to ensure that the ingredient information is
166 submitted to FDA as required by section 904. If there is a failure or refusal to comply with the
167 ingredient listing requirements, then — among other things — the product is deemed misbranded
168 under section 903(a)(10)(A) and therefore subject to refusal of admission into the United States.
169

170 Submissions under section 904(c) are required to be made by the tobacco product manufacturer.
171 An importer of a finished tobacco product for sale or distribution in the United States falls within
172 the definition of a *manufacturer*. An importer that is not a manufacturer required to submit
173 information or reports under section 904(c) may, however, submit the information as an agent on
174 behalf of the manufacturer.
175

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

176

177

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

⁴ 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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185 As defined above, the term *finished tobacco product* means a tobacco product, including all
186 components and parts, sealed in final packaging intended for consumer use (e.g., filters or filter
187 tubes sold separately to consumers or as part of kits). Components and parts that are sold
188 separately from other tobacco products are finished tobacco products if they are sold in final
189 packaging intended for consumer use.

190

191 At this time, with regard to components and parts either sold separately as finished products or as
192 components or parts of other finished products, FDA intends to enforce the ingredient listing
193 submission requirement of section 904(a)(1) only with respect to those components or parts: (1)
194 made or derived from tobacco, or (2) containing ingredients that are burned, aerosolized or
195 ingested during tobacco product use. For example, cigarette paper is burned during use of a
196 cigarette and produces constituents that are inhaled by the smoker, therefore, ingredients in
197 cigarette paper should be submitted to the agency. These components or parts include the
198 following:

199

- 200 • Cigar filler
- 201 • Cigar binder
- 202 • Cigar wrapper
- 203 • Pipe tobacco
- 204 • Waterpipe tobacco
- 205 • E-liquids
- 206 • Cigarette tobacco
- 207 • Cigarette paper
- 208 • Smokeless tobacco
- 209 • Roll-your-own (RYO) tobacco
- 210 • RYO rolling paper
- 211 • RYO tube
- 212 • Cigarette filter that contains any ingredient that burns, aerosolizes, or is ingested during
213 use (e.g., cigarette filter with menthol because the menthol will aerosolize during
214 cigarette smoking).

215

216 Examples of components or parts for which FDA does not intend to enforce the ingredient listing
217 submission requirement of section 904(a)(1) at this time include, but are not limited to, the
218 following:

219

- 220 • Electrical components including, but not limited to, batteries, charging systems, circuit
221 boards, wiring, and connectors
- 222 • System software
- 223 • Digital display, lights, and buttons to adjust settings
- 224 • Connection adapters
- 225 • Cartomizers
- 226 • Coils
- 227 • Wicks

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- 228 • Tanks
- 229 • Mouthpieces
- 230 • Pipes
- 231 • Waterpipes
- 232 • Hoses
- 233 • Bowls
- 234 • Charcoal
- 235 • Cigarette filter that does not contain any ingredient that is burned, aerosolized, or
- 236 ingested during tobacco use
- 237

238 With regard to ingredient listing submissions under section 904(a)(1), FDA intends to focus on
239 components or parts made or derived from tobacco, or containing ingredients that are burned,
240 aerosolized or ingested during tobacco product use because we believe these components and
241 parts of a finished tobacco product are generally the most important in determining the
242 constituents to which users are exposed. However, FDA recognizes that the ingredients of other
243 components and parts can also be important in determining the public health impact of tobacco
244 products. FDA will receive ingredient information for these other components and parts during
245 our pre-market review of finished tobacco products (e.g., Premarket Tobacco Applications and
246 Substantial Equivalence Reports). Should FDA find that additional information is helpful to
247 protect the public health, the Agency may reconsider this compliance policy. We intend to
248 communicate any compliance policy changes by guidance.

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

251 *1. Manufacturer/Importer Identification*

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

- 256 • Your corporate email address
- 257 • Your Data Universal Numbering System (D-U-N-S) number or other unique
258 identifier⁵

⁵ 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.

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- 261 • The facility establishment identifier (FEI) number assigned to your establishment
262 by FDA⁶

263

264 2. *Product Identification*

265

266 Under section 904(a)(1) of the FD&C Act, tobacco product manufacturers or importers are
267 required to submit ingredient lists for “each tobacco product by brand and by quantity in each
268 brand and subbrand.” We interpret this to require that tobacco product manufacturers or
269 importers submit ingredient lists individually for tobacco products that differ in any way.

270

271 If a tobacco product manufacturer or importer sells tobacco products with different
272 brands/subbrands or product sizes⁷ that have identical per weight composition of ingredients
273 with respect to their components and parts, FDA believes that tobacco product manufacturers or
274 importers can satisfy the ingredient listing requirement under section 904(a)(1) by providing one
275 listing that corresponds to multiple products, provided they identify all the different
276 brands/subbrands and product sizes for the associated tobacco products in the submission.
277 Examples of situations allowing a single ingredient listing for multiple products are as follows:

278

- 279 • Identical per weight composition of ingredients for tobacco products sold under
280 multiple brands/subbrands:
- 281 ○ Pipe tobacco with identical per weight composition of ingredients sold under
282 30 brands/subbrands
 - 283 ○ E-liquids with identical per weight composition of ingredients sold under 200
284 brands/subbrands
 - 285 ○ Waterpipe (shisha) tobacco with identical per weight composition of
286 ingredients sold under 15 brands/subbrands
- 287
- 288 • Identical per weight composition of ingredients for tobacco products sold in multiple
289 product sizes:
- 290 ○ E-liquid with identical per weight composition of ingredients sold in volumes
291 of 30mL, 60mL, 90mL or sold in a range of product sizes (e.g., 20mL-100mL)
 - 292 ○ Pipe tobacco with identical per weight composition of ingredients sold in
293 product sizes of 5g, 10g, 50g
 - 294 ○ Waterpipe (shisha) tobacco with identical per weight composition of
295 ingredients sold in product sizes of 100g, 200g, 500g
 - 296 ○ Pouched snus with identical per weight composition of ingredients sold in a
297 can of 12 snus sachets or a can of 15 snus sachets

⁶ You should use the same FEI number for this submission that you have used for prior ingredient listing submissions or establishment registration.

⁷ Product size refers to the volume or quantity of tobacco product itself rather than packaging size.

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299 For e-liquids, FDA believes that tobacco product manufacturers or importers can satisfy the
300 ingredient listing requirement under section 904(a)(1) by providing one listing that corresponds
301 to multiple products if the tobacco product manufacturer or importer sells tobacco products that
302 (1) are identical in chemical composition to one another or (2) are identical in chemical
303 composition to one another except the quantities of propylene glycol (PG), vegetable glycerin
304 (VG), and/or nicotine differ.⁸ For example:

305

- 306 • E-liquids with identical nicotine concentrations (e.g., 0.5 mg/ml nicotine) but varying
307 PG/VG ratios (e.g., 20/80, 50/50, 80/20) and all other ingredients having identical per
308 weight composition.
- 309 • E-liquids with identical PG/VG ratio (e.g., 50/50) but different nicotine concentrations
310 (e.g., 0.5, 1.0 1.5 mg/ml) and all other ingredients having identical per weight
311 composition.
- 312 • E-liquids with varying PG/VG ratios (e.g., 20/80, 50/50, 80/20) and different nicotine
313 concentrations (e.g., 0.5, 1, 2 mg/mL) with all other ingredients having identical per
314 weight composition.

315

316 For e-liquids, the following examples should include separate listings to correspond to each
317 brand/subbrand of tobacco product:

318

- 319 • E-liquids that have identical PG/VG chemical structure, but the nicotine chemical
320 structure is different (e.g., moving from free nicotine to nicotine salt), even with identical
321 per weight composition of all other ingredients.
- 322 • E-liquids that have identical PG/VG chemical structure and identical nicotine chemical
323 structure but where the per weight composition of all other ingredients is different in any
324 way (e.g., increased amount of cherry flavor #1 added when all other ingredient ratios
325 stay the same).
- 326 • E-liquids where the grade of the PG/VG is different in any way (e.g., percent purity
327 changes).

328

329 For each ingredient list, clearly and uniquely identify the product by brand and subbrand,
330 including the type or category of tobacco product (e.g., cigarette, smokeless tobacco product,
331 cigar, ENDS, waterpipe tobacco product) and subcategory.⁹ You should include additional
332 identifiers (e.g., stock-keeping units (SKUs), Universal Product Codes (UPCs), and catalog
333 numbers) as needed to uniquely identify the brand and subbrand of the product.

334

⁸ The per weight composition of the ingredients other than PG/VG and nicotine cannot differ.

⁹ Lists of categories and subcategories are provided on Form FDA 3742 and the eSubmitter submission template. See section III.E “How Do You Submit Ingredient Information.”

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335 Please visit our website at
336 <https://www.fda.gov/tobacco-products/manufacturing/submit-ingredient-listing-tobacco-products>
337 for helpful tools and information.
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340 3. *Ingredient Identification*

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342 Section 904(a)(1) of the FD&C Act sets forth the requirements for submission of ingredient
343 information. The statute requires a listing of all ingredients, including tobacco, substances,
344 compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or
345 other part of each tobacco product as of the date of submission. Ingredients must be specified for
346 each brand and subbrand of tobacco product.
347

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348 FDA considers all ingredients added directly by, or at the direction of, the tobacco product
349 manufacturer to be added by the manufacturer. When the manufacturer knows or intends that an
350 ingredient is formed through a chemical reaction during tobacco product manufacturing, FDA
351 considers the resultant material to be an ingredient that is added by the manufacturer. Similarly,
352 when the manufacturer knows or intends that an ingredient added to any type of packaging will
353 become incorporated into the consumed product, that ingredient is considered to be added by the
354 manufacturer to the tobacco product.
355

356

356 Each listed ingredient is to be uniquely identified so as to distinguish it from similar or related
357 materials. The information necessary to uniquely identify an ingredient varies based upon the
358 type of ingredient as discussed below. For single chemical substances and complex purchased
359 ingredients, FDA also requests that you provide additional information, including the expected
360 functions of each ingredient. By asking for the functions of the ingredient, the agency requests
361 that you identify all expected functions of the ingredient in the final product. As examples, an
362 ingredient may function as a humectant, flavor, or chemo-sensory agent that affects perception of
363 mainstream or side-stream smoke.
364

365

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366 a. *Single Chemical Substance*

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368 Ingredients that are single chemical substances (e.g., sodium chloride, ammonium hydroxide),
369 which may be purchased or prepared in-house and purified, are to be uniquely identified by using
370 a unique scientific name or code, such as the FDA UNII (Unique Ingredient Identifiers) code,
371 Chemical Abstracts Service (CAS) number, or International Union of Pure and Applied
372 Chemistry (IUPAC) name. If you prepare a non-reactive mixture (e.g., a buffer) of single
373 purified chemical substances, you are to report each of the single chemical substances in the
374 mixture individually.
375

376

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

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

388
389 Many ingredients already have FDA UNII. For ingredients that are not already in SRS, you can
390 request an FDA UNII by submitting necessary information to tobacco-UNII@fda.hhs.gov. More
391 information regarding SRS is posted at
392 [http://www.fda.gov/forindustry/datastandards/substanceregistrationsystem-
393 uniqueingredientidentifierunii/default.htm](http://www.fda.gov/forindustry/datastandards/substanceregistrationsystem-uniqueingredientidentifierunii/default.htm).

b. Leaf Tobacco

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

- 400 • the type (e.g., burley, bright, oriental)
- 401 • the variety
- 402 • the cure method (e.g., flue, fire, sun, steam, air) and heat source (e.g., propane,
403 wood)
- 404 • a description of any recombinant DNA technology used to engineer the tobacco
405

406 We consider the cure method and curing heat source necessary to uniquely identify tobacco-
407 derived materials because these factors change the tobacco composition by altering endogenous
408 constituents (e.g., sugars) and, in some circumstances, adding exogenous constituents (e.g., from
409 partially pyrolyzed organic matter), thus resulting in a distinctly different tobacco material.
410 Similarly, we believe that tobacco derived from recombinant DNA technology (e.g., tobacco
411 mosaic virus RNA vector) is intrinsically distinct from unmodified tobacco and that a description
412 of the modification and technology used is, therefore, necessary as part of the identification.
413

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

416
417 Tobacco that has been processed with any chemical, additive, or substance other than potable
418 water is to be reported as described in section III.D.3.c below. Each type of leaf tobacco used in
419 a tobacco product is to be reported as a separate ingredient. For example, if you purchase a
420 tobacco leaf blend or reconstituted tobacco for use in manufacturing a tobacco product, you are
421 to report the blend or reconstituted tobacco as described in section III.D.3.c below. The
422 manufacturer responsible for assembling the blend or reconstituting the tobacco is to submit
423 ingredient lists for its tobacco products and, in doing so, reporting each type of leaf tobacco used
424 in the blend as described in this section.

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c. Complex Purchased Ingredients

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

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

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To further identify complex ingredients that are made to your specifications, FDA requests that you provide the quality (e.g., percent purity, a published standard) of each specified ingredient, the expected function(s) of each specified ingredient, any internal identification number (e.g., SKU, product code) used within your company to reference the complex ingredient, and any additional specifications for the complex ingredient (e.g., release specifications, acceptance criteria, a sample certificate of analysis).

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454

Complex ingredients that are not made to your specifications are also to be uniquely identified. For this, we believe it is necessary to provide:

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- the complete name of the manufacturer.
- 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.

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To further identify complex ingredients not made to your specifications, FDA requests that you provide the quality (e.g., percent purity, a published standard) of the complex ingredient, the expected function(s) of the complex ingredient, and any internal identification number (e.g., SKU, product code) used within your company to reference the complex ingredient. Many of the complex ingredients purchased for use in tobacco products are proprietary blends. You do not need to list any substance contained in a complex purchased ingredient where the ingredient is not made to your specifications. The manufacturer of the complex ingredient,

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467 however, may be subject to ingredient listing reporting requirements, as described in section
468 III.B.

469
470 If you use a complex ingredient provided by multiple suppliers interchangeably in a single
471 tobacco product, you are to report all alternative sources in your ingredient listing, including
472 sufficient information to link the ingredients you consider interchangeable.

473
474 d. Reaction Products

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

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

489
490 4. *Part to Which the Ingredient Is Added*

491
492 Section 904(a)(1) of the FD&C Act requires a listing of ingredients that are added by the
493 manufacturer to the tobacco, paper, filter, or other part. FDA interprets this to mean that
494 manufacturers/importers are to specify whether an ingredient is added to the tobacco, to the
495 paper, to the filter, or to another part of the tobacco product.

496
497 5. *Ingredient Quantity*

498
499 Under section 904(a)(1) of the FD&C Act, you must report ingredients by quantity by brand and
500 subbrand. Under section 904(d) and (e), FDA is required to publish a list of harmful constituents
501 by quantity in each tobacco product by brand and subbrand. FDA intends to rely on consistent
502 reporting from manufacturers and importers to publish this list in a manner that is useful to the
503 public and not misleading to laypersons. Therefore, ingredient information is to be provided
504 using units that are consistent across all products. In addition, the reporting of ingredient
505 quantities is intended to provide the Agency with information to assist with implementation of
506 other provisions of the FD&C Act (e.g., developing tobacco product standards and making
507 substantial equivalence determinations). As such, the quantities need to be reported in consistent
508 units across all products using an absolute measurement that is conserved during chemical
509 reactions. FDA, therefore, interprets the term quantity to mean a unit of mass (i.e., grams with a

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510 standard International System of Units prefix as appropriate) of an ingredient contained in a
511 tobacco product.

512
513 For all tobacco products, quantity is to be expressed in terms of the unit of use for a portioned
514 tobacco product (e.g., one cigarette, one cigar) or per gram of product for a nonportioned tobacco
515 product (e.g., container of loose snuff, reconstituted tobacco, hookah tobacco, hookah charcoal,
516 e-liquids).

517
518 Solvents or other ingredients that are added and subsequently removed during manufacturing are
519 still considered to be added ingredients under section 904(a)(1) of the FD&C Act. As such, the
520 removed ingredient is to be identified and the residual quantity stated (with an appropriate
521 detection limit if the quantity is approximated near zero).

522
523 You are to report all ingredient quantities contained in the tobacco product. You may calculate
524 the quantity based on the added amounts and adjusting for known or intended losses and
525 chemical reactions during manufacturing. Alternatively, the quantity contained in the tobacco
526 product may be derived from laboratory testing.

527
528 You are to report ingredients as a single quantity whenever possible. FDA understands,
529 however, that in some circumstances manufacturers add ingredients based upon manufacturing
530 specifications to affect product characteristics (e.g., to adjust for total sugars or to achieve a
531 particular pH) resulting in the manufacturer adding varying amounts from batch to batch. If you
532 add a particular ingredient in this way, you are to give the quantity by providing both the range
533 of permitted quantities (e.g., add between 1.01 and 1.05 mg to the product) and the targeted
534 outcome (e.g., in order to achieve a pH of 7.1). Both the range of permitted quantities and the
535 targeted outcome are to be derived from the manufacturing specifications for the addition of the
536 ingredient. Where no quantity range is contained in, or can be derived from, manufacturing
537 specifications, it is to be derived from the actual range of historical quantities added to the
538 product.

539
540 Section 904(c) requires the submission of information whenever the quantity of an additive is
541 changed. Almost all ingredients are additives, as that term is defined in section III.A. The
542 quantity before and after the change are reported. A change to the manufacturing specifications
543 for the addition of an additive or to the quantity of an additive as reported constitutes a change
544 triggering the reporting requirements in section 904(c).

545
546 **E. How Do You Submit Ingredient Information?**

547
548 FDA strongly encourages you to make your submission electronically. An electronic submission
549 reduces paper and facilitates efficient (and timely) submissions to the Agency and efficient
550 processing, review, and archiving of the submission once at FDA.

551
552 The FDA eSubmitter tool (eSubmitter) is software provided by FDA for the preparation of
553 electronic submissions. This tool provides a template form to report ingredient data and an

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554 automatic acknowledgement of FDA receipt and allows users to attach large numbers of files,
555 such as PDF documents.

556
557 To use eSubmitter, first download the tool from the FDA Web site at
558 <http://www.fda.gov/ForIndustry/FDAeSubmitter> and install it on your computer.¹⁰ Select the
559 “CTP Tobacco Product Ingredient Listing Submissions” within the eSubmitter program and
560 enter information about your ingredient listing directly into the software. You will not need to
561 prepare additional documents with this information, and you will not need to complete Form
562 FDA 3742.

563
564 You can then use eSubmitter to enter data, attach files, and upload the completed submission
565 through the CTP Portal or FDA Electronic Submissions Gateway (ESG). You will need to apply
566 for a free account to upload data through either the CTP Portal
567 (<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm>) or ESG. Due to the time needed to create new accounts, FDA urges
568 submitters to apply for accounts several weeks in advance of when you intend to submit.
569

570
571 The FDA eSubmitter tool can also streamline the process for submitting updated ingredient
572 listing information required by section 904(c).

573
574 Although FDA strongly encourages electronic submission, Form FDA 3742, an alternative tool
575 for paper submissions, is available at
576 <https://www.fda.gov/about-fda/reports-manuals-forms/forms>

577 Paper submissions may be mailed to:

578
579 Food and Drug Administration
580 Center for Tobacco Products
581 Document Control Center
582 Building 71, Room G335
583 10903 New Hampshire Avenue
584 Silver Spring, MD 20993-0002
585

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

591
592 **F. When Do You Submit Ingredient Information?**
593

¹⁰ The eSubmitter tool requires a computer that runs MS Windows.

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594 Manufacturers and importers of cigarettes, cigarette tobacco, RYO, and smokeless tobacco
595 products that were introduced into interstate commerce before June 22, 2009, were required by
596 section 904(a)(1) of the FD&C Act to submit a list of all ingredients by December 22, 2009.¹¹
597 For cigarettes, cigarette tobacco, RYO, and smokeless tobacco products that were first marketed
598 after June 22, 2009, ingredient lists are due at least 90 days before the product is delivered for
599 introduction into interstate commerce (section 904(c)(1)). Section 904(c) also requires
600 submission of information whenever any additive, or the quantity of any additive, is changed.
601 Submissions under section 904(a)(1) consist of a listing of all ingredients added as of the date of
602 submission.

603
604 The preamble to the deeming rule (81 FR 28974) stated that FDA does not intend to enforce the
605 requirement to submit ingredient listing for manufacturers and importers of newly deemed
606 tobacco products that were introduced into interstate commerce on or before August 8, 2016
607 provided submissions are received by February 8, 2017, or August 8, 2017 for small-scale
608 manufacturers.¹² However, FDA recognizes that some manufacturers of newly deemed products
609 are not familiar with the forms for listing ingredients and, therefore, may need additional time to
610 complete them accurately. In addition, we are aware that some manufacturers may need to
611 prepare and submit multiple lists. Therefore, at this time, for manufacturers and importers of
612 newly deemed tobacco products (21 CFR part 1100) that were introduced into interstate
613 commerce on or before August 8, 2016, FDA does not intend to enforce the requirement to
614 submit ingredient information according to section 904(a)(1) until May 8, 2018. For small-scale
615 manufacturers of newly deemed tobacco products (21 CFR part 1100) that were introduced into
616 interstate commerce on or before August 8, 2016, FDA does not intend to enforce the
617 requirement to submit ingredient information according to section 904(a)(1) until November 8,
618 2018. Additionally, FDA is extending the compliance deadlines with respect to products on the
619 market as of August 8, 2016, by an additional six months for small-scale tobacco product
620 manufacturers and importers in the areas impacted by recent natural disasters to May 8, 2019.¹³
621
622 Tobacco products introduced into interstate commerce after August 8, 2016, are required to
623 submit the ingredient information required by section 904(a)(1) at least 90 days before the
624 product is introduced to interstate commerce.

¹¹ 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.

¹² 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*.

¹³ For a complete list of the areas that have been impacted by recent natural disasters, please visit <https://www.fda.gov/TobaccoProducts/NewsEvents/ucm625171.htm>.

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625
 626 You are not required to submit ingredient lists for tobacco products that you discontinued and
 627 stopped manufacturing before the date of your submission under section 904(a)(1). Such
 628 discontinued products, if manufactured and reintroduced into the market, will, however, require
 629 the ingredient submission under section 904(c)(1). Under that section, you are to submit the
 630 product ingredient list at least 90 days prior to delivery for introduction into interstate commerce.
 631 When a tobacco product manufacturer makes a change to the additives in its cigarettes, cigarette
 632 tobacco, RYO, and smokeless tobacco products after June 22, 2009, sections 904(c)(2) and (c)(3)
 633 require the manufacturer to report these changes. After August 8, 2016, FDA intends to enforce
 634 sections 904(c)(2) and (c)(3) for changes in additives to all tobacco products except for
 635 accessories of newly deemed products.

636
 637 Specifically, under sections 904(c)(2) and (c)(3), if a manufacturer:

- 638 • eliminates or decreases an existing additive, the change must be reported to FDA within 60
 639 days of making the change.
- 640 • adds or increases an additive that FDA has designated in regulations as a tobacco additive
 641 that is not a human or animal carcinogen and is not otherwise harmful to health under the
 642 intended conditions of use, the change must be reported to FDA within 60 days of making
 643 the change.
- 644 • adds a new tobacco additive or increases the quantity of an existing tobacco additive (not
 645 designated as described above), the change must be reported to FDA at least 90 days prior to
 646 making the change.

647
 648

FDA COMPLIANCE POLICY FOR INGREDIENT LIST SUBMISSIONS

	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	• 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

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	FDA Intends to Enforce Ingredient Submissions for These Products	Date of Introduction or Reintroduction	Submission Type	Date to Submit
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, 2018 •FDA does not intend to enforce until November 8, 2018, for small scale manufacturers (or May 8, 2019, for small-scale manufacturers in areas impacted by recent natural disasters)¹⁴
		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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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

¹⁴ For a complete list of the areas that have been impacted by recent natural disasters, please visit <https://www.fda.gov/TobaccoProducts/NewsEvents/ucm625171.htm>.

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664 Exemption 4 (5 U.S.C. 552(b)(4)). The provision contains exceptions allowing disclosure of the
665 information to other officers or employees concerned with carrying out the tobacco products
666 chapter of the FD&C Act and, when relevant, in any proceeding under the tobacco products
667 chapter of the FD&C Act. Section 301(j) of the FD&C Act generally prohibits release of trade
668 secret information obtained by FDA under section 904, among other provisions, outside of the
669 Department of Health and Human Services, except to courts when relevant in any judicial
670 proceeding under the FD&C Act and to Congress in response to an authorized Congressional
671 request.

672
673 FDA's general regulations concerning the public availability of FDA records are contained in 21
674 CFR part 20.

675
676 **V. PAPERWORK REDUCTION ACT OF 1995**

677 This guidance contains information collection provisions that are subject to review by the Office
678 of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C.
679 3501-3520).

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

684 Food and Drug Administration
685 Center for Tobacco Products
686 Document Control Center
687 Building 71, Room G335
688 10903 New Hampshire Avenue
689 Silver Spring, MD 20993-0002

690 An Agency may not conduct or sponsor, and a person is not required to respond to, a collection
691 of information unless it displays a currently valid OMB control number. The OMB control
692 number for this information collection is 0910-0650 (expires 9/30/2022).

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695 DOCUMENT HISTORY

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

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

- 701 • Section II — Background updated to reflect changes in FDA authorities over “deemed”
702 tobacco products arising from deeming rule.
703
- 704 • Section III — Definitions of *accessory*, *component* or *part*, *small-scale tobacco product*
705 *manufacturer*, and *finished tobacco product* added; definition of *importer* and *pouch*
706 updated.
707
- 708 • Section III.B — Section B “Who Submits Ingredient Listing?” compliance policy for
709 cigarettes, cigarette tobacco, RYO, and smokeless tobacco deleted.
710
- 711 • Section III.C — “FDA’s Compliance Policy for Regulated Tobacco Products” added.
712
- 713 • Former section III.C — “What Information Is Submitted With the List of Ingredients?”
714 becomes section III.D.
715
- 716 • Section III.D — Information on Data Universal Numbering System is updated.
717
- 718 • Former section III.D — “How Do You Submit Ingredient Information?” becomes section
719 III.E.
720
- 721 • Section III.E — Information on how to submit ingredient listing information updated.
722
- 723 • Former section III.E — “When Do You Submit Ingredient Listing Information?”
724 becomes section III.F.
725
- 726 • Section III.F — Updated to include submission dates for newly deemed products and
727 provide compliance policy explaining that for tobacco products that were manufactured
728 prior to August 8, 2016, FDA does not intend to enforce the requirement to provide
729 ingredient listing until August 8, 2017, or February 8, 2018, for small-scale
730 manufacturers.
731
- 732 • Former section III.F — “Will the FDA Maintain the Confidentiality of the Ingredient
733 Information You Submit?” becomes section III.G.
734
- 735 • PRA section updated.
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737 **October 2017** — Revised compliance dates (1) to reflect compliance dates in the “Extension of
738 Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule” guidance
739 issued in August 2017 and (2) to provide a six-month extension for tobacco product
740 manufacturers and importers in areas impacted by recent natural disasters.

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

745 **April 2018** — *Listing of Ingredients in Tobacco Products* guidance revised to reflect the
746 following:

- 747 • Section III.D — Clarification regarding ways in which tobacco product manufacturers or
748 importers can provide ingredient listing submissions as required by section 904(a)(1) of
749 the FD&C Act.
750
- 751 • Section III.D — Compliance policy for components and parts either sold separately as
752 finished products or as components or parts of other finished products that are not made
753 or derived from tobacco, or do not contain ingredients that are burned, aerosolized, or
754 ingested during tobacco product use.

755 **November 2018** — Revised compliance date to provide a six-month extension for small-
756 scale tobacco product manufacturers and importers impacted by recent natural disasters.

757