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3 **FDA CIRCULAR**

4 No. _____

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7 **SUBJECT : Vapor Product Standards on Flavoring**
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10 **I. RATIONALE**

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12 The use of flavors in products are generally done to impart taste and/or smell, with an end-
13 view of allowing consumers or users to identify characteristics which may be attractive or
14 appealing. In tobacco and its related products, electronic cigarettes, and vapor products,
15 the use of different flavors such as fruits, candy, coffee, among others, entice nonsmokers,
16 especially youths, to take up smoking and/or vaping. Such flavored products were found
17 to be associated with increased experimentation and trial use, perceptions of reduced harm,
18 higher levels of dependence, and greater difficulty quitting. In order to avoid and/or reduce
19 the health risks introduced by such products, restriction of flavors have been recommended
20 and introduced in multiple jurisdictions.

21
22 Following Republic Act (RA) No. 11467 and its implementing rules and regulations, a
23 prohibition on flavoring in vapor products was declared. To wit, “the manufacture,
24 importation, sale and distribution of vapor products with flavoring other than plain tobacco
25 or plain menthol shall be prohibited”. Further, the Department of Health (DOH), through
26 the Food and Drug Administration (FDA), was mandated to periodically determine and
27 regulate, consistent with evolving and scientific studies, the banning of flavors. Thus, these
28 guidelines are hereby established to ensure the proper implementation of the said rule.

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30 **II. OBJECTIVE**

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32 This Circular aims to establish the standards for flavoring in vapor products pursuant to
33 RA 11467 and its implementing rules and regulations.

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35 **III. SCOPE**

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37 This Circular shall apply to vapor products as defined in RA 11467 and its implementing
38 rules and regulations, and to establishments engaged in the manufacture, importation, sale
39 and distribution of such products.

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41 **IV. DEFINITION OF TERMS**

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43 A. ‘**Additive**’ means a substance, other than tobacco, that is added to a tobacco product, a
44 unit packet or to any outside packaging.
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1 B. **‘Flavoring’** refers to natural/plant/animal products and/or chemically synthesized
2 substances whose significant function is flavoring that imparts smell and/or taste.
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4 C. **‘Characterizing flavor’** means a clearly noticeable smell or taste other than one of
5 plain tobacco and plain menthol, resulting from an additive or a combination of
6 additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, or vanilla,
7 which is noticeable before or during the consumption of the tobacco product.
8

9 D. **‘Plain menthol flavoring’** shall refer to flavorings which impart a plain menthol smell
10 and/or taste.
11

12 E. **‘Plain tobacco flavoring’** shall refer to flavorings which impart a plain tobacco smell
13 and/or taste.
14

15 V. GENERAL GUIDELINES

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17 A. Only plain tobacco or plain menthol shall be allowed in vapor products. The use of
18 plain tobacco and plain menthol in vapor products shall be in accordance to the existing
19 standards on flavoring issued by the FDA.
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21 B. The use of ingredients, including additives, which are basic and/or serve a
22 technological purpose for the manufacture of vapor products consistent with these
23 Guidelines shall be allowed; Provided, that these ingredients do not result in a product
24 with a characterizing flavor, except for the identified basic ingredients in vaping
25 liquids provided in Annex A; Provided, further, that the amount used in the formulation
26 of vapor products does not render it unsafe, injurious, and/or unfit for use.
27

28 C. In the submission of relevant applications for FDA authorizations for vapor products
29 (e.g. FDA Electronic Registration Number [FERN], including the Pre-Application
30 Documentary Evaluation [PADE] and the Product Information File [PIF]), full
31 disclosure of the ingredient listing shall be required. This shall include but not limited
32 to the qualitative and quantitative composition of the vapor product, technological
33 (including organoleptic and intended function in relation to flavoring) function of each
34 ingredient, safety and quality data of the ingredients, among others.
35

36 D. Labelling, packaging, promotional and advertising materials of vapor products shall
37 not include any element or feature which presents the product to have a taste, smell,
38 flavoring other than plain tobacco or plain menthol.
39

40 E. The FDA shall perform post-market surveillance activities in relation to any issued
41 authorization of a vapor product and any available vapor products in the market, to
42 determine the continuous compliance of vapor products to existing laws, rules and
43 regulations. The FDA may utilize consumer reports, FDA-initiated quality product
44 assessments, among others, in assessing the perceived flavor of a vapor product, with
45 the end-view of assessing if the vapor product complies with these Guidelines.

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- F. The FDA shall periodically determine and regulate, consistent with evolving medical and scientific studies, the banning of flavorings. This shall include but not limited to the development of standards and/or test methods to determine perceived taste or smell (e.g. sensory testing) and the development of standards, limits, and/or restrictions for ingredients, including additives and trace chemicals, that are reasonably found to directly or indirectly affect product addictiveness and/or product attractiveness, produce health effects, and/or influence health behavior. Further, the FDA shall not be precluded to assess the appropriateness of menthol and its derivatives as an ingredient in order to regulate its use in vapor products.
- G. Any misrepresentations, misdeclarations, and/or false information submitted and/or reported to the FDA by persons, including market authorization applicants/holders, shall be subject to penalties, including but not limited to, the suspension, revocation, disapproval and/or denial of an application and/or market authorization, and other applicable regulatory actions.

VI. SPECIFIC GUIDELINES

A. Addendum to Vapor Product Refill and Cartridge Standards. The standards for vapor products are hereby updated to include the following:

- 1. Vapor products shall not contain additives that result in a characterizing flavor other than the basic ingredients, as defined in these Guidelines. The use of additives, including sweeteners, that impart a characterizing flavor in any of the components of a vapor product shall be prohibited.
 - a. Identified basic ingredients in vaping liquids which otherwise impart a flavor that are listed in Annex A may be used in the formulation of vapor products.
 - b. The list of allowable plain tobacco and plain menthol flavorings which may form part of the formulation of vapor products are listed in Annexes B and C, respectively. Ingredients not included in Annexes B and C which impart a plain tobacco and plain menthol flavor shall be allowable, provided, that sufficient justification is provided to reasonably determine that such ingredients do not impart flavoring other than plain tobacco and plain menthol.

Methods to determine the flavor (e.g. sensory analysis, chemical analysis) recognized by the FDA, if available, shall be utilized for the purposes of applying for a market authorization of a vapor product. Where a method used is innovative or deviates from the standard methods, the reason and justification for the utilization of such shall be provided. In the absence of the list of standard methods, vapor products shall be tested through an appropriate, reliable, robust, reproducible, and feasible method.

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2. Each ingredient, including additives, included in the formulation of a vapor product shall have a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, transport or holding of such vapor product results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such vapor product.
3. The maximum level of ingredients, including additives, used in vapor products shall be based on the amount reasonably determined to accomplish its intended effect, provided, that such amount of ingredients does not render the product unsafe and/or injurious.

B. Addendum to the List of Documentary Requirements for applications for a FERN Certificate

For applications for a FERN Certificate, the Product Information File requirement shall include the following to assist in the assessment of flavors:

1. In “Product Packaging and Labeling Information”
 - A description of the smell and/or taste intended for the vapor product, including all relevant information presented in intended labelling materials
2. In “Quality Data of the Raw Materials (for refills/cartridges)”
 - Status of authorization, registration, or certification of the raw material by recognized scientific bodies, accredited laboratories, other competent authorities, as applicable
3. In “Technical Specifications of the Finished Product (for refills/cartridges)”

Formulations with flavoring ingredients not provided under Annex B and C shall submit the following:

 - a. Signed and dated Certificate of Analysis of the finished product for the sensory and/or chemical analysis performed for the determination of flavor
 - b. Details of the methodology for the sensory and/or chemical analysis:
 1. Positive control
 2. Negative control
 3. Test procedure, including mode of application, sampling size, test area/facility/equipment, schedule of observation, test duration
 4. Justification for the use of innovative and/or modified methods, if applicable
 5. For test involving human subjects, selection criteria, copy of informed consent form, certification/approval from a Research Ethics Committee, if applicable
 6. Statistical analysis

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- 7. Results and Discussion
- 8. Conclusion
- 9. References

C. Implementation Arrangements. Consistent with the provisions in this Circular, new and existing applications, and previously-authorized vapor products shall be treated as follows:

1. Applications for initial and renewal of FERN Certificates for vapor products filed after the effectivity date of this Circular shall contain the updated requirements as stated in these Guidelines and shall be evaluated accordingly.
2. Pending applications shall be processed in accordance with the existing FERN Certification Guidelines. Should a FERN Certificate be issued for such pending applications, a notice for post-authorization compliance (PAC) shall be issued along with the said Certificate. Compliance to the notice shall be a condition for the continuing validity of the FERN Certificate, wherein the market authorization holders are required to submit the requirements indicated in Section VI.B and shall be subject to the evaluation of the FDA for compliance to the said Guidelines. Failure to comply within the stated period for compliance may be treated as grounds for revocation or suspension of the FERN Certificate.
3. Existing vapor products holding a valid FERN Certificate shall automatically submit the requirements indicated in Section VI.B. within sixty (60) days upon the effectivity of this Circular and shall be subject to the evaluation of the FDA for compliance to the said Guidelines. Failure to comply within the stated period for compliance may be treated as grounds for revocation or suspension of the FERN Certificate.

VII. PENALTY CLAUSE

Any person found in violation of this Circular shall be deemed a violation of RA 3720 as amended by RA 9711, and RA 11467, and shall be penalized accordingly following the Uniform Rules of Procedures laid down under Book III of the Implementing Rules and Regulations of RA 9711.

VIII. REPEALING CLAUSE

Other related issuances inconsistent or contrary to the provisions of this FDA Circular are hereby repealed, amended or modified accordingly.

IX. SEPARABILITY CLAUSE

If any part, term of provision of this Circular shall be declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions shall not be affected

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and this Circular shall be construed as if it did not contain the particular invalid or unenforceable part, term, or provision.

X. EFFECTIVITY

This Circular shall take effect fifteen (15) days after publication in a newspaper of general circulation and filing with the University of the Philippines Office of the National Register (UP-ONAR).

MARIA ROSARIO SINGH-VERGEIRE, MD, MPH, CESO II
Officer-in-Charge
Secretary of Health

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ANNEX A

Basic ingredients in vaping liquids

The following basic ingredients of vaping liquids which otherwise impart flavor may be used for the formulation of vapor products:

1. benzoic acid (CAS 65-85-0)
2. citric acid (CAS 77-92-9)
3. glycerol (CAS 56-81-5)
4. propylene glycol (CAS 57-55-6)
5. sorbic acid (CAS 110-44-1)
6. nicotine (CAS 54-11-5)

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ANNEX B

List of ingredients that may be used to impart a plain tobacco flavor

- 1
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- 4 1. nicotiana tabacum leaf extract (CAS 84961-66-0)
- 5 2. corylone (CAS 80-71-7)
- 6 3. trimethylpyrazine (CAS 14667-55-1)
- 7 4. 2,3-dimethylpyrazine (CAS 5910-89-4)
- 8 5. anethole (CAS 104-46-1, CAS 4180-23-8)
- 9 6. beta-damascone (CAS 35044-68-9, CAS 23726-92-3)
- 10 7. estragole (CAS 140-67-0)
- 11 8. isophorone (CAS 78-59-1)
- 12 9. tetramethylpyrazine (CAS 1124-11-4)
- 13 10. 3-methyl-2-cyclopentenone (CAS 2758-18-1)
- 14 11. 2-hydroxyisophorone (CAS 4883-60-7)
- 15 12. methyl benzoate (CAS 93-58-3)
- 16 13. 2-acetylpyridine (CAS 1122-62-9)
- 17 14. 3,5-xylenol (CAS 108-68-9)
- 18 15. safranal (CAS 116-26-7)
- 19 16. propenylguaethol (CAS 94-86-0)
- 20 17. 4-ethylanisole (CAS 1515-95-3)
- 21 18. gamma-valerolactone (CAS 108-29-2)
- 22 19. 2-acetylfuran (CAS 1192-62-7)
- 23 20. furfuryl alcohol (CAS 98-00-0)
- 24 21. cuminaldehyde (CAS 122-03-2)
- 25 22. 5-methylfurfural (CAS 620-02-0)
- 26 23. 4-methyleneisophorone (CAS 20548-00-9)
- 27 24. ketoisophorone (CAS 1125-21-9)
- 28 25. beta-damascenone (CAS 23696-85-7)
- 29 26. methyl nicotinate (CAS 93-60-7)
- 30 27. veratraldehyde (CAS 120-14-9)
- 31 28. pyridine (CAS 110-86-1)
- 32 29. 2,4-xylenol (CAS 105-67-9)
- 33 30. methyl phenylacetate (CAS 101-41-7)
- 34 31. butyric acid (CAS 107-92-6)
- 35 32. ethyl vinyl ketone (CAS 1629-58-9)
- 36 33. ethyl cyclopentenolone (CAS 21835-01-8)
- 37 34. nonanoic acid (CAS 112-05-0)
- 38 35. geraniol (CAS 106-24-1)
- 39 36. phenethyl isovalerate (CAS 140-26-1)
- 40 37. 2-ethylfuran (CAS 3208-16-0)
- 41 38. ambroxan (CAS 6790-58-5, CAS 100679-85-4, CAS 3738-00-9)
- 42 39. acetylpyrazine (CAS 22047-25-2)
- 43 40. 3,5-dimethoxy-4-hydroxytoluene (CAS 76638-05-07)
- 44 41. cedrol (CAS 77-53-2)
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ANNEX C

List of ingredients that may be used to impart a plain menthol flavor

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1. menthol (CAS 1490-04-6, CAS 89-78-1, CAS 15356-70-4, CAS 491-01-0, CAS 2216-51-5, CAS 490-99-3, CAS 149-64-3)
2. menthone (CAS 10458-14-7, CAS 89-80-5, CAS 14073-97-3, CAS 3391-87-5)
3. menthyl acetate (CAS 16409-45-3, CAS 2230-87-7, CAS 89-48-5, CAS 2623-23-6)
4. cis-carvone oxide (CAS 18383-49-8)
5. pulegone (CAS 89-82-7, CAS 15932-80-6)
6. piperitone (CAS 89-81-6)
7. 2,5-diethyltetrahydrofuran (CAS 41239-48-9)
8. beta-caryophyllene (CAS 87-44-5)
9. delta-cadinene (CAS 483-76-1)
10. nonanal (CAS 124-19-6)
11. alpha-pinene (CAS 80-56-8)
12. para-cymene (CAS 99-87-6)
13. eucalyptol (CAS 470-82-6)
14. isomenthone (CAS 1196-31-2, CAS 491-07-6)
15. isoamyl 2-methylbutyrate (CAS 27625-35-0)
16. isopulegole (CAS 89-79-2, CAS 50373-36-9)
17. p-menthan-1-ol (CAS 21129-27-1)
18. alpha-terpinene (CAS 99-86-5)
19. beta-pinene (CAS 127-91-3)
20. 3-methylcyclohexanone (CAS 591-24-2)
21. caryophyllene oxide (CAS 1139-30-6)
22. beta-bourbonene (CAS 5208-59-3)
23. carvone (CAS 6485-40-1, CAS 99-49-0)
24. carveol (CAS 99-48-9)
25. gamma-terpinene (CAS 99-85-4)
26. isoamyl phenylacetate (CAS 102-19-2)
27. octanol (CAS 111-87-5)
28. methyl salicylate or wintergreen oil (CAS 119-36-8)
29. menthofuran (CAS 494-90-6)
30. perilla alcohol (CAS 536-59-4)
31. 3-octanol (CAS 589-98-0)
32. dihydrocarveol (CAS 619-01-2)
33. trans-3-hexenol (CAS 928-97-2)
34. dihydrocarvyl acetate (CAS 20777-49-5, CAS 57287-13-5)
35. n-ethyl-p-menthane-3-carboxamide (CAS 39711-79-0)
36. sabinene (CAS 3387-41-5)
37. neoisopulegol (CAS 21290-09-5, CAS 89-79-2)
38. thymol (CAS 89-83-8)
39. alpha-humulene (CAS 6753-98-6)
40. carvyl acetate (CAS 97-42-7)

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- 1 41. 2-methyl furan (CAS 534-22-5)
- 2 42. phenethyl alcohol (CAS 60-12-8)

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