

1 [Health Code - Restricting the Sale, Manufacture, and Distribution of Tobacco Products,
2 Including Electronic Cigarettes]

3 **Ordinance amending the Health Code to prohibit the sale by tobacco retail**
4 **establishments of electronic cigarettes that require, but have not received, an order**
5 **from the Food and Drug Administration (FDA) approving their marketing; and**
6 **prohibiting the sale and distribution to any person in San Francisco of flavored**
7 **tobacco products and electronic cigarettes that require, but have not received, an FDA**
8 **order approving their marketing.**

9 NOTE: **Unchanged Code text and uncodified text** are in plain Arial font.
10 **Additions to Codes** are in *single-underline italics Times New Roman font*.
11 **Deletions to Codes** are in *strikethrough italics Times New Roman font*.
12 **Board amendment additions** are in double-underlined Arial font.
13 **Board amendment deletions** are in ~~strikethrough Arial font~~.
14 **Asterisks (* * * *)** indicate the omission of unchanged Code
15 subsections or parts of tables.

16 Be it ordained by the People of the City and County of San Francisco:

17 Section 1. Findings.

18 (a) Despite progress in reducing smoking, tobacco use is still the leading cause of
19 preventable death in the United States. Tobacco kills more than 480,000 people in this
20 country annually – more than AIDS, alcohol, car accidents, illegal drugs, murders, and
21 suicides combined. And beyond this large, impersonal statistic, are countless human beings,
22 whose lives are forever devastated by the irreparable loss of a loved one caused by tobacco
23 use, and the inevitable rupture of family that follows such a loss. And that is to say nothing of
24 the huge financial costs tobacco use places on our health care system, and the constraints on
25 productivity it imposes on our economic system.

1 (b) Electronic cigarettes (or “e-cigarettes”) entered the marketplace around 2007, and
2 since 2014, they have been the most commonly used tobacco product among youth in the
3 United States. The dramatic surge in youth e-cigarette use (“vaping”) is no accident. E-
4 cigarettes are frequently marketed in a variety of flavors with obvious appeal to youth, such as
5 gummy bear, cotton candy, and fruit punch. As of 2017, researchers had identified more than
6 15,500 unique e-cigarette flavors available online. In addition, e-cigarette companies have
7 effectively used marketing strategies, including celebrity endorsements, slick magazine
8 advertisements, social media campaigns, paid influencers, and music sponsorships, to reach
9 youth and young adults. A 2016 study found that 78.2% of middle and high school students—
10 20.5 million youth—had been exposed to e-cigarette advertisements from at least one source,
11 an increase from 68.9% only two years before, in 2014.

12 (c) According to the Centers for Disease Control and Prevention (“CDC”), the number
13 of middle and high school students who reported being current users of tobacco products
14 increased 36%—from 3.6 million to 4.9 million students—between 2017 and 2018. This
15 dramatic increase, which has erased past progress in reducing youth tobacco use, is directly
16 attributable to a nationwide surge in e-cigarette use by adolescents. There were 1.5 million
17 more youth e-cigarette users in 2018 than 2017, and those who were using e-cigarettes were
18 using them more often. Frequent use of e-cigarettes increased from 20 percent in 2017 to 28
19 percent in 2018 among current high school e-cigarette users.

20 (d) The widespread use of e-cigarettes by youth has significant public health
21 consequences. As stated by the Surgeon General, “Most e-cigarettes contain nicotine – the
22 addictive drug in regular cigarettes, cigars, and other tobacco products. Nicotine exposure
23 during adolescence can harm the developing brain – which continues to develop until about
24 age 25. Nicotine exposure during adolescence can impact learning, memory, and attention.
25 Using nicotine in adolescence can also increase risk for future addiction to other drugs. In

1 addition to nicotine, the aerosol that users inhale and exhale from e-cigarettes can potentially
2 expose both themselves and bystanders to other harmful substances, including heavy metals,
3 volatile organic compounds, and ultrafine particles that can be inhaled deeply into the lungs.”

4 (e) And while there is some evidence that the use of e-cigarettes by adults may
5 support smoking cessation under certain circumstances, a 2018 National Academy of
6 Sciences, Engineering, and Medicine report concluded that there was moderate evidence that
7 e-cigarette use in fact *increases* the frequency and intensity of cigarette smoking in the future.

8 (f) In addition, there is a growing body of research concluding that there are significant
9 health risks associated with electronic cigarette use. For example, daily e-cigarette use is
10 associated with increased odds of a heart attack. And the American Lung Association has
11 warned that the inhalation of harmful chemicals through vaping may cause irreversible lung
12 damage and lung disease.

13 (g) To reduce the burden of tobacco use, the City and County of San Francisco (the
14 “City”) licenses tobacco retail establishments. (Health Code Article 19H). In 2017, to address
15 the appeal of flavored tobacco products to youth, the City enacted Ordinance No. 140-17,
16 prohibiting tobacco retail establishments from selling flavored tobacco products. As a result of
17 the referendum process, the ordinance was placed before the voters, who approved the
18 ordinance in June 2018 (Proposition E) by a majority of 68.39%.

19 (h) Notwithstanding these efforts, San Francisco’s youth still access and use tobacco
20 products. According to the most recent Youth Risk Behavior Survey for which local data are
21 available, in 2017, 16.7% of San Francisco’s high school students had tried smoking, 25%
22 had used an electronic cigarette (or “vaped”), and 7.1% reported current e-cigarette use,
23 which is defined as use on at least one day in the past 30 days.

24 (i) Among San Francisco high school students who reported currently using electronic
25 cigarettes, 13.6% reported that they usually purchased their electronic cigarette products in a

1 store. The remaining 86.4% reported that they obtained them from places other than the
2 City’s licensed tobacco retail establishments, including friends, other social sources, and
3 internet e-cigarette vendors.

4 (j) To protect the public, especially youth, against the health risks created by tobacco
5 products, Congress enacted the Family Smoking Prevention and Tobacco Control Act
6 (“Tobacco Control Act”) in 2009. Among other things, the Tobacco Control Act authorized the
7 U.S. Food and Drug Administration (“FDA”) to set national standards governing the
8 manufacture of tobacco products, to limit levels of harmful components in tobacco products
9 and to require manufacturers to disclose information and research relating to the products’
10 health effects.

11 (k) A central requirement of the Tobacco Control Act is premarket review of all new
12 tobacco products. Specifically, every “new tobacco product”—defined to include any tobacco
13 product not on the market in the United States as of February 15, 2007—must be authorized
14 by the FDA for sale in the United States before it may enter the marketplace. A new tobacco
15 product may not be marketed until the FDA has found that the product is: (1) appropriate for
16 the protection of the public health upon review of a premarket tobacco application; (2)
17 substantially equivalent to a grandfathered product; or (3) exempt from substantial
18 equivalence requirements.

19 (l) In determining whether the marketing of a tobacco product is appropriate for the
20 protection of the public health, the FDA must consider the risks and benefits of the product to
21 the population as a whole, including users and nonusers of the product, and taking into
22 account the increased or decreased likelihood that existing users of tobacco products will stop
23 using tobacco products and the increased or decreased likelihood that those who do not use
24 tobacco products will start using them. Where there is a lack of showing that permitting the
25

1 sale of a tobacco product would be appropriate for the protection of the public health, the
2 Tobacco Control Act requires that the FDA deny an application for premarket review.

3 (m) Virtually all electronic cigarettes that are sold today entered the market after 2007,
4 but have not been reviewed by the FDA to determine if they are appropriate for the public
5 health. In 2017, the FDA issued Guidance that purports to give electronic cigarette
6 manufacturers until August 8, 2022 to submit their application for premarket review. The
7 Guidance further purports to allow unapproved products to stay on the market indefinitely,
8 until such time as the FDA complies with its statutory duty to conduct a premarket review to
9 determine whether a new tobacco product poses a risk to public health. In March 2019, the
10 FDA issued draft guidance in which it considered moving the premarket application deadline
11 up by one year for certain flavored e-cigarette products. It is not known when, if ever, this
12 narrow adjustment will become final or will take effect.

13 (n) By the time e-cigarette manufacturers will be required to submit their premarket
14 review applications, e-cigarettes will have been on the market for fifteen years without any
15 FDA analysis of their safety and alleged benefit. If current trends continue, six million more
16 youth in the United States will begin using e-cigarettes between now and then. Until such
17 time as the FDA fulfills its statutory duty to conduct premarket reviews of new tobacco
18 products, a generation of young people will become addicted to tobacco, resulting in an
19 entirely preventable increase in the burdens and tragedies associated with tobacco use. San
20 Francisco is not content to wait until then before addressing, for its residents, what appears
21 from the evidence to be a major public health crisis that is going unattended.

22
23 Section 2. The Health Code is amended by adding new Article 19R, consisting of
24 Sections 19R.1 through 19R.5, to read as follows:

1 **ARTICLE 19R: PROHIBITING THE SALE OF ELECTRONIC CIGARETTES LACKING FOOD**

2 **AND DRUG ADMINISTRATION PREMARKET APPROVAL**

3 **SEC. 19R.1. DEFINITIONS.**

4 *For purposes of this Article 19R, the following terms have the following meanings:*

5 *“Director” has the meaning set forth in Health Code Section 19H.2.*

6 *“Electronic Cigarette” has the meaning set forth in Section 30121 of the California Revenue*
7 *and Taxation Code, as may be amended from time to time.*

8 *“Establishment” has the meaning set forth in Health Code Section 19H.2.*

9 *“New Tobacco Product” has the meaning set forth in 21 U.S.C. § 387j(a)(1), as may be*
10 *amended from time to time.*

11
12 **SEC. 19R.2. SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES LACKING**
13 **FOOD AND DRUG ADMINISTRATION PREMARKET ORDER OF APPROVAL PROHIBITED.**

14 *The sale or distribution by an Establishment of an Electronic Cigarette is prohibited where the*
15 *Electronic Cigarette:*

16 *(a) Is a New Tobacco Product;*

17 *(b) Requires premarket review under 21 U.S.C. § 387j, as may be amended from time to time;*

18 *and*

19 *(c) Does not have a premarket review order under 21 U.S.C. § 387j(c)(1)(A)(i), as may be*
20 *amended from time to time.*

21
22 **SEC. 19R.3. ADMINISTRATIVE REGULATIONS.**

23 *The Director may adopt rules, regulations, or guidelines for the implementation and*
24 *enforcement of this Article 19R.*

1 **SEC. 19R.4. ENFORCEMENT.**

2 *The Director may enforce Section 19R.2 under Articles 19 et seq. of the Health Code, including*
3 *but not limited to Article 19H.*

4
5 **SEC. 19R.5. NO CONFLICT WITH FEDERAL OR STATE LAW.**

6 *Nothing in this Article 19R shall be interpreted or applied so as to create any requirement,*
7 *power, or duty that is preempted by federal or state law.*

8
9 Section 3. Article 19H of the Health Code is amended by adding new Section 19H.14-
10 3, to read as follows:

11
12 **SEC. 19H.14-3. CONDUCT VIOLATING HEALTH CODE ARTICLE 19R**
13 **(PROHIBITING THE SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES LACKING**
14 **FOOD AND DRUG ADMINISTRATION PREMARKET ORDER OF APPROVAL).**

15 *(a) Upon a decision by the Director that the Permittee or the Permittee’s agent or employee*
16 *has engaged in any conduct that violates Health Code Section 19R.2 (Sale or Distribution of Electronic*
17 *Cigarettes Lacking Food and Drug Administration Premarket Order of Approval Prohibited), the*
18 *Director may suspend a Tobacco Sales permit as set forth in Section 19H.19.*

19 *(b) The Director shall commence enforcement under this Section 19H.14-3 by serving either a*
20 *notice of correction under Section 19H.21 or a notice of initial determination under Section 19H.22.*

21
22 Section 4. The Health Code is hereby amended by adding new Article 19S, consisting
23 of Sections 19S.1 through 19S.6, to read as follows:

1 **ARTICLE 19S. PROHIBITING THE SALE AND DISTRIBUTION OF TOBACCO PRODUCTS**

2 **IN SAN FRANCISCO**

3 **SEC. 19S.1. DEFINITIONS.**

4 *For purposes of this Article 19S, the following terms have the following meanings:*

5 *“Characterizing Flavor” has the meaning set forth in Health Code Section 19Q.2.*

6 *“Cigarette” has the meaning set forth in Health Code Section 19Q.2.*

7 *“City” means the City and County of San Francisco.*

8 *“Constituent” has the meaning set forth in Health Code Section 19Q.2.*

9 *“Director” means the Director of Health, or the Director’s designee.*

10 *“Distinguishable” has the meaning set forth in Health Code Section 19Q.2.*

11 *“Distribute” or “Distribution” means the transfer, by any Person other than a common carrier,*
12 *of a Tobacco Product at any point from the place of Manufacture or thereafter to the Person who sells*
13 *the Tobacco Product to an individual for personal consumption.*

14 *“Electronic Cigarette” has the meaning set forth in Section 30121 of the California Revenue*
15 *and Taxation Code, as may be amended from time to time.*

16 *“Flavored Tobacco Product” has the meaning set forth in Health Code Section 19Q.2.*

17 *“Labeling” has the meaning set forth in Health Code Section 19Q.2.*

18 *“New Tobacco Product” has the meaning set forth in 21 U.S.C. § 387j(a)(1), as may be*
19 *amended from time to time.*

20 *“Packaging” has the meaning set forth in Health Code Section 19Q.2.*

21 *“Person” has the meaning set forth in Health Code Section 19H.2.*

22 *“Sell,” “Sale,” and “to Sell” mean any transaction where, for any consideration, ownership of*
23 *a Tobacco Product is transferred from one Person to another, including but not limited to any transfer*
24 *of title or possession for consideration, exchange, or barter, in any manner or by any means.*

25 *“Tobacco Product” has the meaning set forth in Health Code Section 19H.2.*

1
2 **SEC. 19S.2. PROHIBITION ON SALE OR DISTRIBUTION OF TOBACCO PRODUCTS.**

3 (a) No Person shall Sell or Distribute any Flavored Tobacco Product to a Person in San
4 Francisco. There shall be a rebuttable presumption that a Tobacco Product, other than a Cigarette, is
5 a Flavored Tobacco Product if a manufacturer or any of the manufacturer’s agents or employees, in
6 the course of their agency or employment, has made a statement or claim directed to consumers or to
7 the public that the Tobacco Product has or produces a Characterizing Flavor, including, but not
8 limited to, text, color, and/or images on the product’s Labeling or Packaging that are used to explicitly
9 or implicitly communicate that the Tobacco Product has a Characterizing Flavor.

10 (b) No Person shall Sell or Distribute an Electronic Cigarette to a Person in San Francisco
11 where the Electronic Cigarette:

- 12 (1) Is a New Tobacco Product;
13 (2) Requires premarket review under 21 U.S.C. § 387j, as may be amended from time
14 to time; and
15 (3) Does not have a premarket review order under 21 U.S.C. § 387j(c)(1)(A)(i), as may
16 be amended from time to time.

17
18 **SEC. 19S.3. ADMINISTRATIVE REGULATIONS.**

19 The Director may adopt rules, regulations, or guidelines for the implementation of this Article
20 19S.

21
22 **SEC. 19S.4. ENFORCEMENT.**

23 (a) Violations of this Article 19S or of any rule or regulation issued under this Article shall be
24 punishable by administrative fines imposed pursuant to administrative citations. Administrative Code
25 Chapter 100 “Procedures Governing the Imposition of Administrative Fines,” as amended from time to

1 time, shall govern the issuance and enforcement of administrative citations, and collection and review
2 of administrative fines, to enforce this Article and any rule or regulation adopted pursuant to this
3 Article.

4 (b) The City Attorney may at any time institute civil proceedings for injunctive and monetary
5 relief including civil penalties, against any Person for violations of this Article 19S, without regard to
6 whether the Director has assessed or collected administrative penalties.

7 (c) At any time, the Director may refer a case to the City Attorney's Office for civil
8 enforcement, but a referral is not required for the City Attorney to bring a civil action under subsection
9 (b).

10 (d) Any Person that violates any provision of this Article 19S shall be subject to injunctive
11 relief and a civil penalty in an amount not to exceed \$1,000 for each violation, which penalty shall be
12 assessed and recovered in a civil action brought in the name of the people of the City and County of
13 San Francisco by the City Attorney in any court of competent jurisdiction. In assessing the amount of
14 the civil penalty, the court shall consider any one or more of the relevant circumstances presented by
15 any of the parties to the case, including but not limited to, the following: the nature and seriousness of
16 the misconduct giving rise to the violation, the number of violations, the persistence of the misconduct,
17 the length of time over which the misconduct occurred, the willfulness of the misconduct, and the
18 defendant's assets, liabilities, and net worth.

19 (e) The City may recover reasonable attorneys' fees and costs for civil actions brought
20 pursuant to this Section 19S.4.

21 (f) Remedies under this Section 19S.4 are non-exclusive and cumulative to all other remedies
22 available at law or equity.

23
24 **SEC. 19S.5. NO CONFLICT WITH FEDERAL OR STATE LAW.**

1 Nothing in this Article 19S shall be interpreted or applied so as to create any requirement,
2 power, or duty that is preempted by federal or state law.

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4 **SEC. 19S.6. SEVERABILITY.**

5 If any section, subsection, sentence, clause, phrase, or word of this Article 19S, or any
6 application thereof to any person or circumstance, is held to be invalid or unconstitutional by a
7 decision of a court of competent jurisdiction, such decision shall not affect the validity of the remaining
8 portions or applications of the Article. The Board of Supervisors hereby declares that it would have
9 passed this ordinance and each and every section, subsection, sentence, clause, phrase, and word not
10 declared invalid or unconstitutional without regard to whether any other portion of this Article or
11 application thereof would be subsequently declared invalid or unconstitutional.

12
13 Section 5. Effective and Operative Dates.

14 (a) This ordinance shall become effective 30 days after enactment. Enactment occurs
15 when the Mayor signs the ordinance, the Mayor returns the ordinance unsigned or does not
16 sign the ordinance within ten days of receiving it, or the Board of Supervisors overrides the
17 Mayor's veto of the ordinance.

18 (b) This ordinance shall become operative six months after the effective date.

19
20 Section 6. Severability. If any section, subsection, sentence, clause, phrase, or word of
21 this ordinance, or any application thereof to any person or circumstance, is held to be invalid
22 or unconstitutional by a decision of a court of competent jurisdiction, such decision shall not
23 affect the validity of the remaining portions or applications of the ordinance. The Board of
24 Supervisors declares that it would have passed this ordinance and each and every section,
25 subsection, sentence, clause, phrase, and word not declared invalid or unconstitutional

1 without regard to whether any other portion of this ordinance or application thereof would be
2 subsequently declared invalid or unconstitutional.

3
4 Section 7. Undertaking for the General Welfare. In enacting and implementing this
5 ordinance, the City is assuming an undertaking only to promote the general welfare. It is not
6 assuming, nor is it imposing on its officers and employees, an obligation for breach of which it
7 is liable in money damages to any person who claims that such breach proximately caused
8 injury.

9
10 APPROVED AS TO FORM:
11 DENNIS J. HERRERA, City Attorney

12 By: _____
13 ANNE PEARSON
14 Deputy City Attorney

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