



**CITY OF PACIFICA
CITY COUNCIL AGENDA**

**Council Chambers
2212 Beach Blvd
Pacifica, CA 94044**

Mayor Deirdre Martin
Mayor Pro Tem Sue Beckmeyer
Councilmember Sue Vaterlaus
Councilmember Mary Bier
Councilmember Mike O'Neill

January 13, 2020 (MONDAY)

www.cityofpacifica.org

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PLEASE SILENCE CELL PHONES DURING MEETING

7:00 PM OPEN SESSION

Call to Order

Roll Call

Salute to the Flag led by Mayor Martin

SPECIAL PRESENTATIONS

A. Letter of Commendation to Raymond Biagini

B. Letter of Commendation Patrick "Ernie" Delasarte

CONSENT CALENDAR

Persons wishing to address the Council on any Consent Calendar item may do so at this time. Each speaker will be allotted three minutes. Those wishing to address the Council on any item listed on the agenda should submit a speaker card to the City Clerk.

Items on the consent calendar will be adopted by one motion unless a Councilmember or person in the audience requests, before the vote on the motion, to have an item discussed. Time limit on comments is three minutes or less.

1. Approval of Disbursements for 11/15/19 through 11/30/19.
PROPOSED ACTION: Move to approve attached list of disbursements for 11/15/19 through 11/30/19.
2. Approval of Minutes
PROPOSED ACTION: Move to approve the minutes of the regular City Council meeting held on December 9, 2019 and the special City Council meeting held on December 11, 2019.

3. Proclamation Confirming Existence of Local Emergency of the Pacifica Coastline from Westline Drive to the End of Beach Boulevard.
PROPOSED ACTION: Accept report and make a determination that conditions of local emergency continue to exist within the Pacifica Coastline from Westline Drive to the end of Beach Boulevard.
4. Resolution Authorizing the City Manager to Execute Master Agreements with Caltrans
PROPOSED ACTION: Move to adopt a resolution entitled "A Resolution of the City Council of the City of Pacifica Authorizing the City Manager to Execute Master Agreements, Program Supplemental Agreements, Fund Exchange Agreements and/or Fund Transfer Agreement for Federal and/or State Funded Transportation Projects."
5. Approval of the Subdivision Improvement Agreement for the 3-Lot Subdivision at 340 Charing Cross Way, Assessor Parcel Number 016-355-150, Lands of Consult, Design, Build, Inc.
PROPOSED ACTION: Adopt the resolution next in order of the City Council of the City of Pacifica approving the Subdivision Improvement Agreement (SIA) (Exhibit A) for improvements related to the subdivision at the northeast intersection of Charing Cross Way and unimproved Clarendon Road (APN: 016-355-150), and authorize the City Manager to execute the Subdivision Improvement Agreement.

ORAL COMMUNICATIONS

This portion of the Agenda is available for the public to address the City Council on any issue that is not on the Agenda. Any person wishing to address the Council shall be recognized by the Mayor during Oral Communications, provided, however, that during the Oral Communications portion of the agenda, only items not on the agenda for that meeting may be addressed. All remarks shall be addressed to the Council as a body and not to any member thereof. Councilmembers shall not enter into debate with speakers under Oral Communications. A maximum time of three minutes will be allowed for any speaker. Pursuant to Pacifica Municipal Code Title 2, Chapter 1, Section 2-1.118 any person making impertinent, slanderous, or profane remarks or who becomes boisterous while addressing the Council shall be called to order by the presiding officer and, if such conduct continues, may, at the direction of the presiding officer, be ordered barred from further audience before the Council during the meeting.

COUNCIL COMMUNICATIONS

The purpose of Council Communications is for Councilmembers to inform each other of items of potential interest to other Councilmembers, such as interagency meetings.

STAFF COMMUNICATIONS

The purpose of Staff Communications is for the City Manager to offer announcements as appropriate.

PUBLIC HEARINGS

6. Introduction of an Ordinance to Amend Various Articles of Chapter 4 of Title 9 of the Pacifica Municipal Code Relating to Accessory Dwelling Units; and Introduction of an Ordinance to Amend Chapter 11 of Title 6 and Chapter 15 of Title 8 of the Pacifica Municipal Code Relating to Sewer Fees and Traffic Impact Mitigation Improvement Fund for Highway One Improvements; and Other Related Pacifica Municipal Code Provisions to Incorporate California Law Updates Related to Accessory Dwelling Unit and Junior Accessory Dwelling Unit Construction (Text Amendment TA-117-19; File No. 2019-031) and Finding Adoption of the Ordinances Exempt from the California Environmental Quality Act (CEQA); the Planning Commission Recommended Approval of the Zoning Amendments by a Vote of 6-1 on December 16, 2019.

PROPOSED ACTION:

- 1) Move to waive the first reading and introduce by title only "An Ordinance of the City Council of the City of Pacifica Amending Chapter 11 of Title 6 (Sewer Connection Charges) and Chapter 15 of Title 8 (Traffic Impact Mitigation Improvement Fund For Highway One Improvements) and Finding Adoption of the Ordinance Exempt from the California Environmental Quality Act (CEQA)"
- 2) Move to waive the first reading and introduce by title only "An Ordinance of the City Council of the City of Pacifica Amending Article 4 of Chapter 4 (R-1 Single Family Residential District); Amending Article 4.5 of Chapter 4 (Accessory Dwelling Units); Amending Article 5 of Chapter 4 (R-2 Two-Family Residential District); Amending Article 6 of Chapter 4 (R-3 Multiple-Family Residential District); Amending Article 10 of Chapter 4 (C-1 Neighborhood Commercial District); Amending Article 11 of Chapter 4 (C-2 Community Commercial District); Amending Article 22 of Chapter 4 (Planned Development District (P-D); Amending Article 23 of Chapter 4 (General Provisions and Exceptions); Amending Article 30 of Chapter 4 (Nonconforming Lots, Structures, and Uses); Amending Article 32 of Chapter 4 (Site Development Permits); Amending Article 34 of Chapter 4 (Variances); Amending Article 43 of Chapter 4 (Coastal Zone Combining District), Amending Chapter 5 (Growth Control), and Amending Chapter 7 (Historic Preservation) of Title 9 of the Pacifica Municipal Code (Text Amendment TA-117-19), and Finding Adoption of the Ordinance Exempt from the California Environmental Quality Act (CEQA)"

CONSIDERATION

7. Consideration of a Prohibition on the Sale of Flavored Tobacco Products and Electronic Cigarettes ("E-Cigarettes")

PROPOSED ACTION: Accept the report and provide direction to the City Manager regarding developing an ordinance prohibiting the sale of flavored tobacco products and electronic cigarettes ("E-Cigarettes") in Pacifica, for the Council's future consideration.

8. Adopt resolutions nominating two Priority Development Areas (PDA) and one Priority Production Area (PPA) within the City; and authorize the City Manager to confirm intent to adopt Vehicle Miles Traveled (VMT) Reduction policies for the Sharp Park Specific Plan PDA.

PROPOSED ACTION:

- 1) Adopt the Resolution nominating the Sharp Park Specific Plan area as a Priority Development Area and authorize the City Manager to confirm intent to adopt Vehicle

- Miles Traveled (VMT) Reduction policies for this area; and
- 2) Adopt the Resolution nominating the Skyline Corridor area as Priority Development Area; and
 - 3) Adopt the Resolution nominating the North Palmetto area as a Priority Production Area.
9. Consideration and Adoption of Resolution Approving Second Amendment to Employment Agreement between the City of Pacifica and Kevin Woodhouse as City Manager
PROPOSED ACTION: Adopt Resolution Approving the Second Amendment to Employment Agreement between the City of Pacifica and Kevin Woodhouse.
10. 2020 City Council Liaison and Committee Assignments
PROPOSED ACTION: Update the City Council Liaison and Committee Assignments for 2020.

ADJOURN

NOTICE: If you challenge a city's zoning, planning or other decision in court, you may be limited to raising only those issues you or someone else raised at the public hearing described in this notice, or in written correspondence delivered to the City Council at, or prior to, the public hearing. Judicial review of any city administrative decision may be had only if a petition is filed with the court not later than the 90th day following the date upon which the decision becomes final. Judicial review of environmental determinations may be subject to a shorter time period for litigation, in certain cases 30 days following the date of the final decision

The City of Pacifica will provide assistance for disabled citizens upon at least 24 hours advance notice to the City Manager's Office (650) 738-7301, or send request via email to: coffeys@ci.pacifica.ca.us if you need sign language assistance or written material printed in a larger font or taped, advance notice is necessary. All meeting rooms are accessible to the disabled.

The Pacifica Municipal Code is available on line at the City's website (www.cityofpacificca.org/municode);

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Posted agendas:

Agendas are posted no later than Friday prior to the City Council meeting date, at the entrance to City Hall, 170 Santa Maria Avenue

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City Hall, 170 Santa Maria Avenue, 2nd Floor

Council meetings:

Agendas are available at the City Council meeting

HOW TO REACH YOUR GOVERNMENT OFFICIALS

- Governor Gavin Newsom, State Capitol Building, Sacramento CA 95814 (916) 445-2841
- State Senator Jerry Hill, 1528 So. El Camino Real, Suite 303, San Mateo CA 94402 (650) 212-3313
- Assembly Member Kevin Mullin, 1528 South El Camino Real, Suite 302 San Mateo, CA 94402 (650) 349-2200
- Congresswoman Jackie Speier, 155 Bovet Road, Suite 780, San Mateo CA 94402 (650) 342-0300
- Senator Kamala Harris, 50 United Nations Plaza, San Francisco CA 94102 (213) 894-5000
- Senator Dianne Feinstein, #1 Post Street, Suite 2450, San Francisco CA 94104 (415) 393-0707
- President Donald J. Trump, 1600 Pennsylvania Ave. NW, Washington DC 20500

CITY COUNCIL

- Mayor Deirdre Martin, martind@ci.pacifica.ca.us
- Mayor pro Tem, Sue Beckmeyer, beckmeyers@ci.pacifica.ca.us
- Councilmember Sue Vaterlaus, vaterlauss@ci.pacifica.ca.us
- Councilmember Mary Bier, bierm@ci.pacifica.ca.us
- Councilmember Mike O'Neill, o'neillm@ci.pacifica.ca.us



**CITY OF PACIFICA
COUNCIL AGENDA SUMMARY REPORT**

1/13/2020

SUBJECT:

Consideration of a Prohibition on the Sale of Flavored Tobacco Products and Electronic Cigarettes ("E-Cigarettes")

RECOMMENDED ACTION:

Accept the report and provide direction to the City Manager regarding developing an ordinance prohibiting the sale of flavored tobacco products and electronic cigarettes ("E-Cigarettes") in Pacifica, for the Council's future consideration.

STAFF CONTACT:

Daniel Steidle, Chief of Police
(650) 738-7314
steidled@pacificapolice.org

BACKGROUND:

Concerns regarding health problems caused by smoking and second-hand smoke and the attractiveness of flavored tobacco products to minors has created public health policy discussions at the local, state and national level. In response, some local jurisdictions have adopted ordinances prohibiting the sale of flavored tobacco products. At the request of Councilmembers Bier and O'Neill, this report to Council provides information regarding this issue for the City Council's consideration. The City Manager is seeking direction from the Council whether the Council would like to consider at this time a draft ordinance prohibiting the sale of flavored tobacco products in Pacifica. This report provides information about this health issue, what other jurisdictions have done, City staff resources and priorities, as well as legal costs to develop a draft ordinance, and other information relevant to the Council's consideration of this topic.

DISCUSSION:

Definitions

Discussion of a potential ordinance regarding flavored tobacco products requires definition of certain terms, including a definition of flavored tobacco products. As a baseline for a full discussion on the subject, below are some relevant definitions which currently exist in Chapter 15 of Title 4 (Smoking Prohibitions) and Chapter 31 of Title 5 (Tobacco Retailing) of the Pacifica Municipal Code relating to Tobacco:

Electronic Smoking Device

"Electronic smoking device" means an electronic and/or battery operated device, which can provide an inhalable dose of nicotine, cannabis, whether recreational or medicinal, or other vaporized liquids to the person inhaling the device, including, but not limited to, an electronic cigarette, cigar, pipe, or hookah. "Electronic smoking device" does not

include any product specifically approved by the United States Food and Drug Administration for the use in the mitigation, treatment, or prevention of disease.

Tobacco or nicotine product:

"Tobacco or nicotine product" means any substance containing tobacco leaf, including, but not limited to, cigarettes, cigars, pipe tobacco, hookah tobacco, snuff, chewing tobacco, dipping tobacco, or any other preparation of tobacco; and any electronic cigarette or other electronic device used to generate smoke; and any product or formulation of matter containing biologically active amounts of nicotine that is manufactured, sold, offered for sale, or otherwise distributed with the expectation that the product or matter will be introduced into the human body, but does not include any cessation product specifically approved by the United States Food and Drug Administration for use in treating nicotine or tobacco dependence.

Tobacco Retailer:

"Tobacco Retailer" means any person who sells, offers for sale, or does or offers to exchange for any form of consideration, tobacco, tobacco products, or tobacco paraphernalia, or who distributes free or low cost samples of tobacco products or tobacco paraphernalia. "Tobacco retailing" shall mean the doing of any of these things. This definition is without regard to the quantity of tobacco, tobacco products, or tobacco paraphernalia sold, offered for sale, exchanged, or offered for exchange.

The following definitions are codified in Chapter 4.99 of Title 4 of the San Mateo County Code of Ordinances relating to regulation of flavored tobacco and are not currently included in the Pacifica Municipal Code:

Flavored tobacco product: *Any tobacco product that contains a constituent that imparts a characterizing flavor.*

Constituent: *Any ingredient, substance, chemical or compound, other than tobacco, water, or reconstituted tobacco sheet that is added by the manufacturer to a tobacco product during the processing, manufacture, or packaging of the tobacco product.*

Characterizing Flavor: *A distinguishable taste or aroma, or both, other than the taste or aroma of tobacco, imparted by a tobacco product or any byproduct produced by the tobacco product. Characterizing flavors include, but are not limited to, tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, menthol, mint, wintergreen, herb, or spice. A tobacco product shall not be determined to have a characterizing flavor solely because of the use of additives or flavorings or the provision of ingredient information. Rather, it is the presence of a distinguishable taste or aroma, or both, as described in the first sentence of this definition, that constitutes a characterizing flavor.*

While the foregoing definitions are not determinative of what definitions may be used in any possible ordinance they provide everyone with a basic understanding of what the relevant terms may mean.

Youth and Flavored Tobacco

Flavored tobacco products have been the subject of negative publicity as they are known to be attractive to minors. According to Tobacco Free Kids, a non-profit organization that works to reduce youth access to tobacco and reduce tobacco related deaths:

- Tobacco industry documents show that the tobacco companies have a long history of developing and marketing flavored tobacco products as “starter” products that attract kids.
- Flavors improve the taste and reduce the harshness of tobacco products, making them more appealing and easier for beginners to try the product and ultimately become addicted.
- Menthol cools and numbs the throat, reducing the harshness of cigarette smoke, thereby making menthol cigarettes more appealing to youth who are initiating tobacco use.
- According to FDA’s Tobacco Product Scientific Advisory Committee (TPSAC), menthol cigarettes increase the number of children who experiment with cigarettes and the number of children who become regular smokers, increasing overall youth smoking.
- Flavors can create the false impression that a tobacco product is less harmful than it really is.

In the same publication, Tobacco-Free Kids provided the following statistics that were collected in a 2019 survey of middle and high school students:

- 81% of youth who have ever used tobacco products initiated with a flavored product.
- 72.3% of youth tobacco users have used a flavored tobacco product in the past month.
- At least two-thirds of youth tobacco users report using tobacco products “because they come in flavors I like.”

Recent media attention has focused on JUUL Labs Inc. (“JUUL”), a company that markets electronic smoking devices, including e-cigarettes. The electronic smoking devices accept pods containing flavored liquid that is smoked, producing a taste. Third-party companies have produced additional flavor pods that are compatible with JUUL electronic smoking devices. On September 9, 2019, the U.S. Food and Drug Administration (FDA) issued a warning letter to JUUL for marketing unauthorized modified risk tobacco products by engaging in labeling, advertising, and/or other activities directed to consumers, including a presentation given to youth at a school (See Attachment 1).

Health Issues Relating to Use of E-Cigarettes

Health issues have long been chronicled related to smoking of tobacco products and second-hand smoke, and more recently, smoking using e-cigarette devices (“vaping”). Health concerns related to smoking were recently considered by the City Council in the Multi-Unit Housing Smoking ordinance which was adopted by Council on September 9, 2019.

Health issues related to tobacco e-cigarettes and ingestion of THC by vaping have gained national attention after a string of deaths and hospitalizations involving the use of these products. The Center for Disease Control (CDC) is currently investigating the cause of these illnesses. Research into the causes of these illnesses has not concluded nor identified definitively a specific cause(s). However, the CDC reports illnesses at a much higher level occur as a result of consuming THC vaping products that are black market purchased than THC products purchased legally. While THC-only vaping products that contain cannabis oils tested at State approved facilities are legal to sell in legal cannabis retail operations, the CDC and FDA

recommend that people should not use THC-containing e-cigarette, or vaping products, particularly from informal sources like friends, family, or in-person or online sellers.

A February 2019 publication by the Harvard Medical School stated advocates of vaping have promoted it as a way to help cigarette smokers to quit. The article indicated that although giving up nicotine products altogether might be the ultimate goal, there may be health benefits to a smoker who becomes a long-term vaper instead, though this remains unproven.

While the FDA has stated e-cigarettes are unhealthy, they have recommended smokers who have chosen to vape not return to cigarette smoking, but rather should seek FDA approved smoking cessation medications.

Legislation/Policy

The Family Smoking Prevention and Tobacco Control Act ("Act"), passed by the United States Congress in October 2009, bans cigarettes with flavors other than menthol or tobacco. Flavored e-cigarettes, e-liquids, cigars, hookah, and chewing tobacco are unregulated. However, the Act also provides that every "new tobacco product" (defined to include any tobacco product not on the market in the United States as of February 15, 2007), must be authorized by the FDA in a premarket review before it may enter the marketplace in the United States. Where it can be shown that there is a lack of showing that permitting the sale of the product would be appropriate for the protection of the public health, the Act requires that the FDA deny the application for premarket review.

On September 11, 2019, the Trump Administration announced that as part of its ongoing work to tackle the epidemic of youth e-cigarette use, the FDA intends to finalize a compliance policy that would prioritize the agency's enforcement of the premarket authorization requirements for non-tobacco-flavored e-cigarettes, including mint and menthol, clearing the market of unauthorized, non-tobacco-flavored e-cigarette products. At the time of this announcement, Health and Human Services Secretary Alex Azar said the administration intends to "clear the market" of all flavored electronic cigarettes to address the increasing rates of electronic cigarette use by youth. On December 20, 2019, a federal bill was signed by the President raising the smoking (including vaping) minimum age to 21 years.

On January 2, 2020, the FDA issued a policy relating to enforcement against certain unauthorized flavored e-cigarette products that appeal to kids, including fruit and mint flavors. Further, the FDA has advised they intend to prioritize enforcement against illegally marketed e-cigarette products by focusing on the following groups of products that do not have premarket authorization:

- Any flavored, cartridge-based e-cigarette product (other than a tobacco- or menthol-flavored product);
- All other e-cigarette products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
- Any e-cigarette product that is targeted to minors or likely to promote use of e-cigarette by minors.

At this point, the FDA has not completed premarket review of any e-cigarette products but is currently reviewing several applications.

In 2019, California Senator Jerry Hill introduced SB38, a bill to ban flavored tobacco products, aimed at reducing the use of electronic cigarettes by minors. In May of 2019, Senator Hill shelved the bill after lobbying by the tobacco industry watered the bill down to the extent it was opposed by health organizations.

On September 16, 2019, Governor Newsome instructed state regulators to “reduce youth vaping consumption” by finding ways to ban illegal and counterfeit vaping products. The Governor also set aside \$20 million for a vaping awareness campaign and instructed state health officials to develop signs warning against the hazards of vaping to be placed at retailers and on advertising for e-cigarettes and accessories. Governor Newsome has stated that he does not have the authority to ban flavored vaping products, but would work with legislators in 2020 to ban them.

In November 2019, San Francisco voters defeated Measure C, which would have partially overturned San Francisco’s ordinance related to e-cigarettes and flavored tobacco. In San Francisco, certain e-cigarette sales are prohibited anywhere the sale of tobacco products are prohibited. In addition, flavored tobacco product sales are prohibited (including flavored e-cigarettes). Cannabis vaping products are legal to sell anywhere cannabis sales are permitted. Beginning in late January 2020, San Francisco will suspend the sale of electronic cigarettes, except for those e-cigarettes that have gone through required premarket review by the FDA.

San Mateo County Ordinances

South San Francisco: Prohibits sale of flavored tobacco and e-cigarettes (flavored or not) except by “adult-use” businesses. Adult-use is defined as only allowing persons inside the business 21+ years of age unless accompanied by parent or guardian. South San Francisco is the only jurisdiction in San Mateo County that prohibits all e-cigarette sales, except by adult use businesses. The South San Francisco ordinance can be located at:

<https://www.ssf.net/home/showdocument?id=17432>

County of San Mateo (Including jurisdictions of Portola Valley, Half Moon Bay and San Carlos): Prohibits sale of flavored tobacco products, including flavored e-cigarettes. Tobacco flavored e-cigarette sales are permitted. The San Mateo County ordinance can be located at:

https://library.municode.com/ca/san_mateo_county/codes/code_of_ordinances?nodeId=TIT4S_AHE_CH4.99SAFLT0PRPHSAT0PRPR

Staff Time/Priority Considerations

Adoption of an ordinance prohibiting the sale of flavored tobacco products in Pacifica will require staff and City Attorney time to author the ordinance. Staff research time would be required to further explore ordinance options, based on the desired content of the ordinance as directed by Council.

If an ordinance were adopted, staff time would be required to develop a plan for educating the community and local businesses that sell the prohibited products. Enforcement of the ordinance would require staff time to conduct compliance inspections of businesses by the City, likely falling upon the Police Department and/or Code Enforcement. Currently, there are 29 businesses in the City that hold City of Pacifica Tobacco Retail Permits.

The City Manager estimates that developing an ordinance for the Council’s consideration and, if adopted, developing and implementing outreach, and on-going enforcement, would be manageable with existing staff resources, but would additionally burden staff’s workload related

to other program implementations and enforcement activities, such as the single-use plastic utensils program, enforcement of the multi-unit dwelling smoking prohibition, or development of other ordinances such as the bee-keeping ordinance updates. However, eventually all of these programs would still be addressed.

Legal Considerations

Under the California Constitution, a "county or city may make and enforce within its limits all local, police, sanitary, and other ordinances and regulations not in conflict with general laws." (Cal Const art XI, §7). Additionally, cities are authorized by State law to enact local tobacco retail licensing ordinances and allows for the suspension or revocation of a license for a violation of any state tobacco control law. (Cal. Bus. & Prof. Code § 22971.3). As a result of the foregoing authority, a number of cities and counties in California have exercised their local legislative power to regulate businesses that sell flavored tobacco and e-cigarette products to address the significant health and safety concerns which arise from use of flavored tobacco and e-cigarettes.

While many cities and counties have adopted ordinances regulating sales of flavored tobacco and/or e-cigarettes, there appear to have been only two local jurisdictions (City and County of San Francisco and City of Livermore) that have faced significant legal challenges from an e-cigarette manufacturer, JUUL. As discussed above, the City and County of San Francisco received a referendum challenge, Measure C, which would have partially overturned San Francisco's ordinance related to e-cigarettes and flavored tobacco. Measure C was primarily funded by JUUL but prior to the November, 2019 election, JUUL decided to pull funding for the Measure and it failed. Additionally, the City of Livermore received a similar referendum challenge. Although the referendum had qualified for the March 3, 2020 ballot, the referendum backed by JUUL was withdrawn in October, 2019. JUUL has indicated that these withdrawals are due to a change in new leadership causing the company to review its policies.

Due to the continuing use of flavored tobacco and e-cigarettes among youth, it is very likely that State legislators will continue to draft legislation on a state-level to address this issue.

Conclusion

Marketing flavored tobacco products towards minors and consumption of flavored tobacco products by minors has sparked many communities to adopt local ordinances prohibiting the sales of these products. However, state or federal level bans have not yet been approved, but are under consideration. The information provided in this staff report is intended to guide the Council's consideration of whether the City should expend staff time and money developing an ordinance and, if so, whether to pursue it now, or wait to see how state or federal legislation evolves first. If the Council is interested in directing the City Manager to return with a draft ordinance prior to a state or federal action, then the following variables need to be clarified:

1. Should the ordinance be focused only on the prohibition of flavored tobacco sales?
2. Should the ordinance prohibit all e-cigarette sales that have not undergone FDA premarket review, or only flavored tobacco cartridges?
3. Should the ordinance prohibit cannabis e-cigarette products?
4. Other variables?

ALTERNATIVE ACTION:

Request further research/information from staff prior to providing direction regarding a potential ordinance. Council may also desire to accept the report and request no further action from staff, or to wait to see how state or federal legislation evolves first.

RELATION TO CITY COUNCIL GOALS AND WORK PLAN:

Consideration of a prohibition on the sale of flavored tobacco products and e-cigarettes in Pacifica resonates with the City Council Goal of “A Healthy and Compassionate Community.”

FISCAL IMPACT:

The City Attorney’s Office estimates that legal costs relating to preparation of an ordinance would vary depending on the variables identified by Council and range from \$6,000 (if Council directs staff to prepare an ordinance to only prohibit flavored tobacco) up to \$10,000 (if Council directs staff to also include in the ordinance a prohibition of cannabis e-cigarette products).

ORIGINATED BY:

Police

ATTACHMENT LIST:

Attachment 1- JUUL Warning Letter (PDF)

WARNING LETTER

JUUL Labs, Inc.

MARCS-CMS 590950 – SEPTEMBER 09, 2019

Delivery Method:

VIA UPS and Electronic Mail

Product:

Tobacco

Recipient:

Mr. Kevin Burns

CEO

JUUL Labs, Inc.

560 20th Street

San Francisco, CA 94107-4344

United States

Issuing Office:

Center for Tobacco Products


10903 New Hampshire Avenue

Silver Spring, MD 20993

United States

WARNING LETTER

Dear Mr. Burns:

The Center for Tobacco Products of the U.S. Food and Drug Administration (FDA) reviewed testimony from the July 24-25, 2019 hearing on “Examining JUUL’s Role in the Youth Nicotine Epidemic,” of the Subcommittee on Economic and Consumer Policy of the Committee on Oversight and Reform of the United States House of Representatives (“House Subcommittee”), documents from FDA’s September 24-28, 2018 inspection of JUUL Labs, Inc.’s (JUUL) headquarters in San Francisco, California, JUUL’s submissions to the Agency, and JUUL’s website, <https://www.juullabs.com> (<https://www.juullabs.com>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>), and determined that JUUL products, which are electronic nicotine delivery system (ENDS) products, are manufactured, marketed, advertised, labeled, and offered for sale or distribution to customers in the United States. Under section 201(rr) of the Federal Food,

Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 321(rr)), as amended by the Family Smoking Prevention and Tobacco Control Act, these products are tobacco products because they are made or derived from tobacco and intended for human consumption. Certain tobacco products, including ENDS products (e.g., e-cigarettes and e-liquids), are subject to FDA jurisdiction under section 901(b) of the FD&C Act (21 U.S.C. § 387a(b)).

Based on our review of the information described above, FDA has determined that JUUL adulterated its products under section 902(8) of the FD&C Act (21 U.S.C. § 387b(8)) by selling or distributing them as modified risk tobacco products without an FDA order in effect that permits such sale or distribution.

Modified Risk Tobacco Products Without an Appropriate FDA Order in Effect are Adulterated

Our review of testimony from the July 24-25, 2019 House Subcommittee hearing, documents from FDA's inspection of JUUL's headquarters, JUUL's submissions to the Agency, and JUUL's website, <https://www.juullabs.com> (<https://www.juullabs.com>). [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>), revealed that your firm has engaged in labeling, advertising, and/or other activities directed to consumers, in which JUUL explicitly and/or implicitly has represented that JUUL products are free of a substance, have a reduced level of or exposure to a substance, and/or that JUUL products present a lower risk of tobacco-related disease or are less harmful than one or more other commercially marketed tobacco products.

The July 24-25, 2019 House Subcommittee hearing included the following evidence:

1. A JUUL representative speaking with students at his presentation stated that JUUL “was much safer than cigarettes” and that “FDA would approve it any day.”^[1]
2. The JUUL representative speaking with students at his presentation called JUUL “totally safe.”^[2]
3. The JUUL representative speaking with students at his presentation stated that a student “...should mention JUUL to his [nicotine-addicted] friend...because that’s a safer alternative than smoking cigarettes, and it would be better for the kid to use.”^[3]
4. The JUUL representative speaking with students at his presentation stated, “FDA was about to come out and say it [JUUL] was 99% safer than cigarettes...and that...would happen very soon....”^[4]

Referring to your ENDS products as “99% safer” than cigarettes, “much safer” than cigarettes, “totally safe,” and “a safer alternative than smoking cigarettes” is particularly concerning because these statements were made directly to children in school. Our concern is amplified by the epidemic rate of increase in youth use of ENDS products, including JUUL's products, and evidence that ENDS products contribute to youth use of, and addiction to, nicotine, to which youth are especially vulnerable.^[5]

In addition, your “Letter from the CEO” states: “[JUUL's] simple and convenient system incorporates temperature regulation to heat nicotine liquid and deliver smokers the satisfaction that they want without the combustion and the harm associated with it.” On April 25, 2018, your letter appeared in an email that JUUL sent to a parent in response to her complaint that the firm sold JUUL products to her child. On May 8, 2018, your letter appeared on JUUL's website, <https://www.juullabs.com> (<https://www.juullabs.com>). [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>).^[6] This letter provides further confirmation of the evidence from the hearing testimony that JUUL has marketed JUUL products as modified risk tobacco products.

A tobacco product is considered a “modified risk tobacco product,” *inter alia*, if its label, labeling, or advertising explicitly or implicitly represents that: (1) the product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products; (2) the product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or (3) the product or its smoke does not contain or is free of a substance (section 911(b)(2)(A)(i) of the FD&C Act (21 U.S.C. § 387k(b)(2)(A)(i))); or where the manufacturer has taken any action directed to consumers through media or otherwise, other than by means of the tobacco product’s label, labeling, or advertising, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances (section 911(b)(2)(A)(iii) of the FD&C Act (21 U.S.C. § 387k(b)(2)(A)(iii))).

Under section 911(a) of the FD&C Act (21 U.S.C. § 387k(a)), no person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product without an FDA order in effect under section 911(g) of the FD&C Act (21 U.S.C. § 387k(g)). A modified risk tobacco product application under section 911(d) of the FD&C Act (21 U.S.C. § 387k(d)) is required to provide scientific evidence and other information to support issuance of an order under section 911(g) of the FD&C Act (21 U.S.C. § 387k(g)). A product that is in violation of section 911(a) of the FD&C Act (21 U.S.C. § 387k(a)) is adulterated under section 902(8) of the FD&C Act (21 U.S.C. § 387b(8)).

JUUL has marketed its ENDS products as modified risk tobacco products because JUUL’s labeling, advertising, and/or other actions directed to consumers (examples of which are referenced above), represent, or would be reasonably expected to result in consumers believing, that the products present a lower risk of tobacco-related disease or are less harmful than one or more other commercially marketed tobacco products; contain a reduced level of a substance or present a reduced exposure to a substance; and/or do not contain or are free of a substance or substances. JUUL adulterated its products under section 902(8) of the FD&C Act (21 U.S.C. § 387b(8)) by selling or distributing them as modified risk tobacco products without an appropriate FDA order in effect under section 911(g) of the FD&C Act (21 U.S.C. § 387k(g)) that permits such sale or distribution.

Conclusion

The violations discussed in this letter do not necessarily constitute an exhaustive list. To the extent you have not already done so, you should immediately correct the violations that are referenced above, as well as violations that are the same as or similar to those stated above, and take any necessary actions to bring your tobacco products into compliance with the FD&C Act. It is your responsibility to ensure that your tobacco products, all related labeling and advertising, and all other activities by JUUL directed to consumers, such as in any media in which you advertise and any retail establishments, comply with each applicable provision of the FD&C Act and FDA’s implementing regulations. Failure to ensure compliance with the FD&C Act may result in FDA initiating further action, including, but not limited to, civil money penalties, seizure, and/or injunction. Please note that any adulterated and misbranded tobacco products offered for import into the United States are subject to detention and refusal of admission.

Please submit a written response to this letter within 15 working days from the date of receipt describing your corrective actions, including the dates on which you discontinued the violative promotion, labeling, advertising, sale, and/or distribution of these tobacco products. In your written response, please also describe your plan for maintaining compliance with the FD&C Act, including your plan to prevent violations that are the same as or similar to those stated above, such as through, for example, new internal controls and training. You can find the FD&C Act through links on FDA’s homepage at <http://www.fda.gov> (<http://www.fda.gov>). If you do not believe that your products are in violation of

section 911 of the FD&C Act (21 U.S.C. § 387k), please provide us with your reasoning and provide any and all scientific evidence and data, if any, that support that your statements and representations do not explicitly or implicitly convey that JUUL products pose less risk, are less harmful, present reduced exposure, or are safer than other tobacco products.

Please note your reference number, RW1901168, in your response and direct your response to the following address:

Anthony Villa, Senior Regulatory Counsel
Office of Compliance and Enforcement
FDA Center for Tobacco Products
c/o Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions about the content of this letter, please contact Anthony Villa at (301) 796-7385 or via email at Anthony.Villa@fda.hhs.gov (<mailto:Anthony.Villa@fda.hhs.gov>).

Sincerely,

/s/

Ann Simoneau, J.D.

Director

Office of Compliance and Enforcement

Center for Tobacco Products

VIA Electronic Mail

cc:

Jerry Masoudi

Chief Legal Officer, JUUL Labs, Inc.

(b)(6)

[1] Hearing, July 24, 2019, Testimony of Ms. Meredith Berkman (PAVe co-founder), at minutes 52:27 – 53:31 (<https://youtu.be/m3iEMrAd83o>) (<https://youtu.be/m3iEMrAd83o>) [⌕ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer)).

[2] Hearing, July 24, 2019, Testimony of Mr. Caleb Mintz (son of Ms. Meredith Berkman, PAVe co-founder), at minutes 1:18:50 – 1:19:11 (<https://youtu.be/m3iEMrAd83o>) (<https://youtu.be/m3iEMrAd83o>) [⌕ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer)).

[3] Hearing, July 24, 2019, Testimony of Mr. Phillip Fuhrman (son of Ms. Dorian Fuhrman, PAVe co-founder), at minutes 1:20:20 – 1:21:14 (<https://youtu.be/m3iEMrAd83o>) (<https://youtu.be/m3iEMrAd83o>) [⌕ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer)).

[4] Hearing, July 24, 2019, Testimony of Mr. Phillip Fuhrman, at minutes 1:21:45 – 1:22:02 (<https://youtu.be/m3iEMrAd83o>) (<https://youtu.be/m3iEMrAd83o>) [⌕ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer)).

[5] As discussed in the March 2019 Draft Guidance: Modifications to Compliance Policy for Certain Deemed Tobacco Products, “[R]ecent data show a significant increase in minors’ use of ENDS products...For example, data from the NYTS [National Youth Tobacco Survey] show that, between 2017 and 2018, current e-cigarette use among high school students increased 78 percent (11.7 percent to 20.8 percent, $p<0.05$)...These data represent an increase of an estimated 1.32 million high school students reporting past 30-day e-cigarette use in one year. Current e-cigarette use among middle school students also increased by 48 percent over the same time period (3.3 percent to 4.9 percent, $p<0.05$), an increase of an estimated 180,000 middle school students reporting past 30-day e-cigarette use in one year...[.]” (<https://www.fda.gov/media/121384/download>), at p. 8)

[6] See, e.g., “Letter from the CEO” from Mr. Kevin Burns, CEO, JUUL Labs, Inc. (<https://www.juulabs.com>) (<https://www.juulabs.com>), <http://www.fda.gov/about-fda/website-policies/website-disclaimer>) (May 8, 2018).

➡ More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)