Significant Regulatory, Policy, and Enforcement Developments: 2019

LAUREN FARRUGGIA AND JONATHAN HAVENS*

A new decade is upon us, as are substantial federal and state policy, regulatory, and enforcement developments for the tobacco, hemp-derived products, and food and beverage industries. Such developments include:

- President Trump signed H.R. 1865 into law late last year, which bans the sale of tobacco products to anyone under the age of 21;
- The Trump Administration (the Administration) finalized its partial ban on flavored e-cigarette products, while the U.S. Food and Drug Administration (FDA or the Agency) issued its enforcement policy on unauthorized flavored e-cigarettes that appeal to children;
- FDA issued its Final Rule outlining new graphic warnings for tobacco products;
- The U.S. Department of Agriculture (USDA) approved the first set of state and tribal plans for domestic production of hemp under the U.S. Domestic Hemp Production Program;
- FDA issued Warning Letters to fifteen companies for illegally selling products containing cannabidiol (CBD), and published a revised Consumer Update, in which the Agency detailed specific safety concerns and questions about CBD products; and
- FDA issued final Nutrition Facts label (NFL) rule guidance, just days before the NLR went into effect for companies with annual sales over $10 million.

MINIMUM AGE FOR TOBACCO SALES INCREASED TO 21

On December 20, 2019, President Trump signed H.R. 1865 into law, changing the "Minimum Age of Sale of Tobacco Products" within Section 906(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) from 18 to 21 years of age.[1]This new requirement applies to the sale of cigarettes, cigars, and e-cigarettes, alike. Nineteen states and over 500 localities had previously adopted 21 as the minimum tobacco

* Lauren Farruggia is an associate at Saul Ewing Arnstein & Lehr LLP, resident in the firm's Washington, D.C. office, where she is a member of the firm's Life Sciences, Cannabis Law, and Food, Beverage & Agribusiness practices. Jonathan Havens is a partner at Saul Ewing Arnstein & Lehr LLP, resident in the firm's Baltimore and Washington, D.C. offices, where he serves as the co-chair of both the firm's Cannabis Law and Food, Beverage & Agribusiness practices, and is a member of the firm's Life Sciences practice.

[1] Further Consolidated Appropriations Act of 2020, Pub. L. No. 116-94, (2019).

purchase age, but in light of recent concerns surrounding youth access to, among other things, e-cigarette products, national uniformity is a significant public health win.

This change went into effect immediately: FDA published a note on its website the same day President Trump signed the legislation into law, explaining that "[i]t is now illegal for a retailer to sell any tobacco product—including cigarettes, cigars and e-cigarettes—to anyone under 21."[2] The Health and Human Services (HHS) Secretary is tasked with publishing a final rule in the Federal Register within 180 days of enactment to update associated regulations with the new minimum age requirement.[3] At the time this article was published, HHS had not yet issued this regulation.

PARTIAL BAN OF FLAVORED E-CIGARETTES ANNOUNCED; FDA ISSUES ENFORCEMENT POLICY

After first announcing its intention to ban most flavored e-cigarette products in September 2019, in an effort to curb youth access to e-cigarettes (and, seemingly in response to vaping-related deaths and injuries), the Administration finally moved forward with a "partial" flavor ban on January 2, 2020.[4] FDA had previously prepared one version of the ban in early November 2019 for President Trump's review (which would have required candy, fruit, mint, and possibly menthol flavors to be removed from the market within thirty days, and which would have outlined an enforcement policy addressing such products that lack premarket authorization), but, because of supposed political concerns raised by the vaping community, the Administration declined to move forward.[5] The vaping community's "#wevapewevote" social media campaign, along with analyses of the number of vapers in swing states that was posted on Twitter and elsewhere, seems to have been quite effective in convincing the Administration to reconsider its approach to the partial flavor ban.

FDA's final version of the partial ban includes an enforcement policy on "unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint."[6] Tobacco and menthol flavored e-cigarettes are excluded from the policy, as are e-liquids used in open tank systems available at vape shops, which FDA concluded will "balance the public health concerns related to youth use of ENDS

---

[2] *Selling Tobacco Products in Retail Stores*, U.S. FOOD & DRUG ADMIN. (Dec. 20, 2019), https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/selling-tobacco-products-retail-stores.

[3] *See supra*, note 1, § 603(b)(1).

[4] *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Sept. 11, 2019), https://www.hhs.gov/about/news/2019/09/11/trump-administration-combating-epidemic-youth-ecigarette-use-plan-clear-market.html.

[5] *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products*, U.S. FOOD & DRUG ADMIN. (Sept. 11, 2019), https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non.

[6] *FDA Finalizes Enforcement Policy on Unauthorized Flavored Cartridge-Based E-Cigarettes That Appeal to Children, Including Fruit and Mint*, U.S. FOOD & DRUG ADMIN. (Jan. 2, 2020), https://www.fda.gov/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children; U.S. FOOD & DRUG ADMIN., ENFORCEMENT PRIORITIES FOR ELECTRONIC NICOTINE DELIVERY SYSTEM (ENDS) AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION: GUIDANCE FOR INDUSTRY (April 2020) [hereinafter ENFORCEMENT GUIDANCE], https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market

products with considerations regarding addicted adult cigarette smokers who may try to use ENDS products to transition away from combustible tobacco products."[7] Companies that have not ceased "manufacture, distribution and sale of" these identified, unauthorized products within thirty days of publication of the partial ban would be subject to FDA enforcement action.[8]

By way of background, on July 28, 2017, FDA announced a comprehensive plan to overhaul the Agency's tobacco regulatory efforts.[9] Under this plan, the deadline for marketing applications for non-combusted products such as electronic nicotine delivery systems (ENDS) or e-cigarettes was August 8, 2022;[10] however, the U.S. District Court for the District of Maryland moved this deadline up significantly, to May 12, 2020.[11] But, as long as an e-cigarette product was on the market as of August 8, 2016 (i.e., the effective date of FDA's Deeming Rule, which subjected tobacco products to the FD&C Act's regulatory controls), the manufacturer could continue to market its product until the May 2020 marketing application deadline (and during FDA's review of its application).[12]

Despite this deadline, however, FDA has indicated that it would begin to prioritize enforcement of the following products starting on February 6, 2020:

- Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);
- All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
- Any ENDS product that is targeted to minors or likely to promote use of ENDS by minors.[13]

A few key takeaways and observations:

- It appears that FDA, and state and local inspectors contracted by the Agency, started retail enforcement sweeps beginning on February 6, 2020.[14] Retailers should have planned to stop selling all flavored (except tobacco- and menthol-flavored) cartridge-based products.

---

7 ENFORCEMENT GUIDANCE, *supra* note 6, at 5.

8 *See supra*, note 6.

9 *FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death*, U.S. FOOD & DRUG ADMIN. (July 27, 2017), https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death.

10 U.S. Food & Drug Admin., FDA's Comprehensive Plan for Tobacco and Nicotine Regulation (July 31, 2019), https://www.fda.gov/tobacco-products/ctp-newsroom/fdas-comprehensive-plan-tobacco-and-nicotine-regulation.

11 ENFORCEMENT GUIDANCE, *supra* note 6, at 5.

12 *Id.* at 5–6.

13 *Id.* at 3.

14 *See, e.g.*, *Warning Letter to City Vapes Premium eJuice Inc.*, U.S. FOOD & ADMIN. (Feb. 28, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/city-vapes-premium-ejuice-inc-604021-02282020.

The exact definition of "cartridge-based" is not yet clear. Also unclear is which ENDS products are currently undergoing premarket review at FDA. This information is important, as a flavored product may remain on the market as long as a premarket tobacco product application (PMTA) is pending before FDA.

- The partial ban seems to be a win for JUUL, the maker of popular pod-based vaping products. The San Francisco-based company decided to remove many of its popular flavors mid-last year in response to pressure from regulators and public health advocates.[15] The partial ban should serve to re-even the playing field for JUUL.
- Not only is the ban merely partial, as tobacco- and menthol-flavored products are carved out from it, but it is not necessarily permanent. If and when FDA approves a flavored ENDS product PMTA, that product could come back on the market. With that said, it is not clear if a flavored, cartridge-based product could ever meet the rigorous "public health" standard by which FDA is required to review tobacco products.
- While the partial, and possibly temporary ban has been viewed as a win for the vaping industry, it is important to recognize that *all* vaping products—cartridge-based, open tank, and otherwise—will eventually need to undergo PMTA review. Again, for products on the market as of August 8, 2016, the PMTA submission deadline is May 12, 2020. The PMTA process is not for the faint of heart. As noted by the U.S. Small Business Administration in the Deeming Rule, FDA estimated that PMTA costs would be between $28,566 and $2,595,224 per ENDS delivery unit, with an average cost of $466,563 and between $12,112 and $398,324 per e-liquid used in such devices, with an average cost of $131,643.[16] These projections may be grossly underestimated, and the real costs may indeed be substantially higher. As suggested by the estimates above, a separate PMTA is needed for each delivery unit model, as well as for each and every flavor SKU. SBA further noted that over ninety percent of tobacco manufacturers and tobacco retailers are small businesses, meaning that these costs will be particularly significant for the vast majority of industry.[17] And, finally, although some vape shops might not realize it, if they mix e-liquid flavors, FDA considers them to be manufacturers. Unless they cease flavor mixing—something that vape shops have used to attract customers and achieve profitability—they, too, will need to submit PMTAs.

---

[15] Allison Aubrey, *Juul Suspends Sales of Flavored Vapes And Signs Settlement To Stop Marketing To Youth*, NPR (Oct. 17, 2019), https://www.npr.org/sections/health-shots/2019/10/17/771098368/juul-suspends-sales-of-flavored-vapes-and-signs-settlement-to-stop-marketing-to-.

[16] *FDA Seeks Comments on Premarket Tobacco Product Applications Proposed Rule*, U.S. SMALL BUS. ADMIN., OFFICE OF ADVOCACY (Oct. 1, 2019), https://advocacy.sba.gov/2019/10/01/fda-seeks-comments-on-proposed-pmta-and-recordkeeping-requirements/.

[17] *Id.*

FDA ISSUES FINAL RULE ON NEW GRAPHIC WARNINGS FOR TOBACCO PRODUCTS

On August 15, 2019, FDA published a court-ordered proposed rule that would mandate graphic health warnings for cigarette packaging and advertisements to "promote greater public understanding of the negative health consequences of smoking."[18]

FDA's proposed warnings are graphic and feature thirteen "photo-realistic" images of "some of the lesser-known, but serious health risks of cigarette smoking," including secondary harm to children, fatal lung disease in non-smokers, head and neck cancer, reduction of blood flow (which can lead to erectile dysfunction or require digit or limb amputation), and type 2 diabetes. On March 18, 2020, FDA published its final rule and an accompanying Guidance document outlining the submission process for required cigarette rotational packaging plans, which must provide for "the random and equal display and distribution of the required warnings on cigarette packaging and quarterly rotation of the required warnings in cigarette advertising."[19] Although the final rule only finalized eleven of the original thirteen proposed warnings, the final rule still require the images to occupy the top fifty percent of both the front and rear panels of cigarette packages and at least twenty percent of the area at the top of cigarette advertisements.[20] Companies have fifteen months (or by June 18, 2021) to comply with these requirements.[21]

This proposal represents FDA's latest effort in cigarette packaging reform since Congress required the Agency to take action after it passed the 2009 Family Smoking Prevention and Tobacco Control Act (the Act). In June 2011, FDA first issued a final rule requiring graphic warnings for cigarette packaging and advertisements;[22] however, this rule was quickly challenged by the tobacco industry under First Amendment grounds and was overturned by the U.S. Court of Appeals for the District of Columbia (D.C. Circuit) in *R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin.*, 696 F.3d 1205 (D.C. Cir. 2012). Applying the intermediate scrutiny standard articulated in *Central Hudson Gas & Elec. Co. v. Public Serv. Comm. of N.Y.*, 447 U.S. 557 (1980), the D.C. Circuit determined that FDA did not put forth substantial evidence that its graphic warnings would "directly" reduce smoking by a "material degree," so FDA could not compel tobacco companies to use its graphic warnings on cigarette labeling.

But, in October 2016, several public health and medical groups filed a lawsuit against FDA again, arguing that the Agency unlawfully delayed issuing a final rule

---

[18] *Cigarette Health Warnings*, U.S. FOOD & DRUG ADMIN. (Aug. 15, 2019), https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-health-warnings.

[19] *FDA Requires New Health Warnings for Cigarette Packages and Advertisements*, U.S. FOOD & DRUG ADMIN. (Mar. 17, 2020), https://www.fda.gov/news-events/press-announcements/fda-requires-new-health-warnings-cigarette-packages-and-advertisements; 85 Fed. Reg. 15,638, 15,710 (Mar. 18, 2020).; U.S. FOOD & DRUG ADMIN., SUBMISSION OF PLANS FOR CIGARETTE PACKAGES AND CIGARETTE ADVERTISEMENTS: GUIDANCE FOR INDUSTRY 4 (Mar. 2020) [hereinafter CIGARETTE PACKAGE GUIDANCE], https://www.fda.gov/media/133839/download.

[20] CIGARETTE PACKAGE GUIDANCE, *supra* note 19, at 6.

[21] 85 Fed. Reg. at 15,638.

[22] 76 Fed. Reg. 36,628, 36,777 (June 22, 2011).

requiring warnings for cigarette packaging and advertisements in violation of the Act.[23] In March 2019, Judge Indira Talwani of the U.S. District Court for the District of Massachusetts ordered FDA to publish a proposed rule by August 2019 and a final rule by March 2020.[24] Seemingly in anticipation of a subsequent industry challenge to the latest set of warnings, FDA has made a concerted effort to support its final rule through a "comprehensive, science-based research and development process," citing over 200 studies in the proposed and final rules. Even still, proving that the proposed graphic warnings will be effective in reducing smoking will not be easy, and time will tell whether another challenge is in the works as firms work to comply with the packaging plan requirements.

USDA APPROVES HEMP PLANS FOR FIRST SET OF STATES AND INDIAN TRIBES

In late October 2019, USDA issued its long-awaited hemp production interim final rule, which provided states and Indian tribes with the opportunity to submit plans concerning the monitoring and regulation of hemp production for USDA's approval.[25] On December 27, 2019, USDA approved the first set of plans submitted by Louisiana, New Jersey, and Ohio, and the Flandreau Santee Sioux, Santa Rosa Cahuilla, and La Jolla Band of Luiseno tribes.[26] USDA approved these plans in the middle of its public comment period on the interim final rule, which was extended until January 29, 2020.[27]

USDA approval is significant, as hemp growers must be licensed or authorized under an applicable state, tribe, or USDA production program in order to produce hemp. At least seventeen additional states and twenty Indian tribes have submitted, or are in the process of drafting, a hemp plan for USDA's review.[28] USDA appears to be making plan approval decisions on a rolling basis now that the docket has closed for public comment.

---

[23] *See supra*, note 13.

[24] Mem. and Order Granting Injunctive Relief, *Am. Acad. Of Pediatrics et al. v. FDA*, No. 16-11985 (D. Mass. 2019).

[25] 84 Fed. Reg. 58,522, 58,564 (Oct. 31, 2019).

[26] *USDA Approves First State and Tribal Hemp Production Plans*, U.S. DEP'T OF AGRIC. (Dec. 27, 2019), https://www.ams.usda.gov/content/usda-approves-first-state-and-tribal-hemp-production-plans.

[27] *USDA Extends U.S. Domestic Hemp Production Program Interim Final Rule Comment Period to January 29*, U.S. DEP'T OF AGRIC. (Dec. 17, 2019), https://www.ams.usda.gov/content/usda-extends-us-domestic-hemp-production-program-interim-final-rule-comment-period-january.

[28] *Status of State and Tribal Hemp Production Plans for USDA Approval*, U.S. DEP'T OF AGRIC. (last visited Mar. 19, 2020), https://www.ams.usda.gov/rules-regulations/hemp/state-and-tribal-plan-review.

FDA ISSUES NEW ROUND OF CBD WARNING LETTERS, REVISES CONSUMER UPDATE

On November 25, 2019, FDA announced[29] that it had issued Warning Letters to fifteen companies for illegally selling products containing CBD.[30] Simultaneous with this round of CBD-related enforcement, the Agency also published a revised Consumer Update, in which it detailed specific safety concerns and questions about CBD products.[31] Although FDA raised these concerns and questions before (e.g., at its May 31, 2019 CBD hearing and in a previous version of the Consumer Update), the Agency was a bit more specific in these most recent communications.

The November 2019 Warning Letters maintain the themes evident in earlier enforcement sweeps from 2015, 2016, 2017, and 2018, but also include new language representing FDA's determination that CBD is not presently recognized as generally recognized as safe (GRAS) in human or animal food.

In the most recent Warning Letters, FDA cited problematic labeling and claims observed on retailers' websites, in social media posts, and in customer testimonials. While the Agency certainly continued to target aggressive therapeutic claims aimed at vulnerable populations (such as children or the chronically ill) as it has in the past, notably, the Agency also addressed less aggressive claims, including use to manage "aches and pain," "minor pain that comes with exercise," skin irritation, inflammation, promoting a "calming effect," and improving mood. In spite of this new scrutiny, however, we have not yet seen standalone enforcement action for these traditionally lower-risk claims; each target made aggressive therapeutic claims, as well.

FDA took issue with many retailers' CBD dietary supplement labeling, noting that, simply because a product may be otherwise properly labeled as a dietary supplement, once it contains CBD, the product is no longer a permissible supplement. Among the myriad reasons why CBD firms may decide to label their ingestible products as supplements is that they are required to do so by state law (e.g., New York). Just as in the less aggressive claims context, discussed above, simply labeling a CBD product as a supplement is not currently grounds for receiving a Warning Letter, although FDA has made clear that CBD products are excluded from the dietary supplement definition under Section 201(ff)(3)(B) of the FD&C Act.[32] There would have to at least be an aggressive claim before FDA would issue a Warning Letter for a product being labeled as a supplement. The Agency also cited many retailers for use of health claims in the

---

[29] *FDA Warns 15 Companies for Illegally Selling Various Products Containing Cannabidiol as Agency Details Safety Concerns*, U.S. FOOD & DRUG ADMIN. (Nov. 25, 2019), https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details.

[30] *Warning Letters and Test Results for Cannabidiol-Related Products*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products (last visited Sept. 24, 2020).

[31] *What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis (last visited Sept. 24, 2020).

[32] *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)*, U.S. FOOD & DRUG ADMIN. (current as of August 3, 2020), https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd.

pet product context, rendering such products unapproved new animal drugs under the FD&C Act.

Ultimately, it is clear that the Agency is trying to curb the recent explosion of CBD products. These Warning Letters emphasize that no health claims, no matter how seemingly innocuous, are permissible. CBD ingestibles marketed without health claims are likely lower risk, but because of FDA's concern about marketing to vulnerable user populations, companies choosing to market in this space should be exceedingly careful, as the Agency could police such sales more aggressively in the future.

Although the Agency's cannabis and cannabis-derived products Consumer Update is not new—FDA issued it for the first time in July 2019—this version contains some enhancements to FDA's previously articulated positions. Based on what the Agency has characterized as a "lack of scientific information supporting the safety of CBD in food," FDA indicated definitively in this version, for the first time, that it cannot conclude that CBD is GRAS among qualified experts for its use in human or animal food. By way of background, any substance that is intentionally added to food is a food additive that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive.

Moreover, the Agency again detailed the potential risks associated with using CBD products, including: liver injury, affecting the metabolism of other drugs, and sedation or drowsiness caused by use with alcohol or other depressants. FDA also reiterated potential side effects that CBD could cause, including: changes in alertness, gastrointestinal distress, and changes in mood. Finally, the Agency again noted that there are several unknowns related to CBD, including: what happens if you take CBD daily for sustained periods of time, what is the effect of CBD on the developing brain, what are the effects of CBD on the developing fetus or breastfed newborn, how does CBD interact with herbs and botanicals, and does CBD cause male reproductive toxicity in humans. Again, while FDA had previously teed up potential risks, side effects, and unknowns related to CBD, the Agency has further specified these points in the most recent iteration of the Consumer Update.

Historically, the Agency has focused its CBD enforcement on marketers making aggressive therapeutic claims (e.g., for treatment of Alzheimer's disease, psychiatric disorders, and diabetes). In a potential foreshadowing of expanded enforcement, the Agency indicated in its update that, in addition to continuing to pursue such products, it will also monitor the marketplace for any product that poses a risk to public health, including those with dangerous contaminants (e.g., pesticides, heavy metals, delta-9 tetrahydrocannabinol (THC)) and those marketed to vulnerable populations (e.g., the elderly, children, adolescents, pregnant, and lactating women).

FDA's revised Consumer Update does not discuss use of, or risks associated with, topical CBD products, use of which has been expressly permitted by FDA in the past (absent therapeutic claims). Accordingly, topical products without claims continue to be permissible, although it is worth monitoring this area closely. The Agency's focus instead remains on CBD added to human foods and supplements, and animal foods and feeds, which still remain, in the Agency's view, illegal to market under the FD&C Act.

While it cannot be denied that the Agency was more specific in its safety assessments and questions in its Consumer Update and Warning Letters than it had

been previously, FDA's latest concerns in the CBD context are nothing new. The Agency continues to remain focused on aggressive therapeutic claims, but has now suggested that it will monitor products for general therapeutic claims, as well, particularly when directed at vulnerable populations.

CANNABIS AND CBD POSTSCRIPT

Although the following developments occurred in 2020, we would be remiss if we did not discuss them in this piece.

More recently:

- On March 5, 2020, FDA issued a report to Congress, as required by the Further Consolidated Appropriations Act, related to the Agency's progress toward obtaining and analyzing data to help determine a policy of enforcement discretion and the process in which CBD meeting the definition of hemp will be evaluated for use in FDA-regulated products (the Report).[33] In short, the Report represents anywhere from a "non-event" to potentially good news for the CBD industry. Informing the sense that the Report is a "non-event" is that many of the points FDA raised in the Report (e.g., lack of sufficient CBD research, potential concerns regarding cumulative exposure, and the inability to market CBD ingestibles (despite the very limited amount of enforcement, absent aggressive disease claims)) are ones the Agency has addressed previously. As far as the Report being potentially good news for industry, the Agency stated in the Report that it is "actively considering potential pathways for certain CBD products to be marketed as dietary supplements . . . [including] actively evaluating potential rulemaking to allow CBD in dietary supplements."[34] Depending on the parameters of such prospective regulations, a CBD supplement rulemaking could provide more certainty to industry and could allay fears of enforcement action being taken simply because a product is offered in a supplement format. However, evaluating a potential rulemaking is not the same as drafting a rule. Thus, the sense that FDA will for certain issue a CBD rulemaking this year (or ever) may be misguided.
- On July 8, 2020, FDA's report to Congress, "Sampling Study of the Current Cannabidiol Marketplace to Determine the Extent That Products are Mislabeled or Adulterated," was made public.[35] The Agency's July 8 report to Congress focuses almost entirely on its

---

[33] U.S. Food & Drug Admin., Report to U.S. House Committee on Appropriations and U.S. Senate Committee on Appropriations—Cannabidiol (CBD)—Report in Response to Further Consolidated Appropriations Act, 2020, https://www.scribd.com/document/450303002/FDA-CBD-report#download (last visited Sept. 24, 2020).

[34] *Id.* at 2, 9.

[35] U.S. Food & Drug Admin., Report to the U.S. House Committee on Appropriations and the U.S. Senate Committee on Appropriations—Sampling Study of the Current Cannabidiol Marketplace to Determine the Extent That Products are Mislabeled or Adulterated, https://hempindustrydaily.com/wp-content/uploads/2020/07/CBD-Marketplace-Sampling_RTC_FY20_Final.pdf.

CBD product sampling efforts.[36] It provides little in terms of policy or overall conclusions regarding the extent to which currently-marketed CBD products are mislabeled or adulterated, which was supposed to be the purpose of the report, per Congress's direction in the Further Consolidated Appropriations Act. For the first time in the report, though, FDA details its testing efforts prior to the passage of the 2018 Farm Bill. Also detailed in the Report, in 2019, FDA identified thirty-four CBD products for the testing of certain characteristics, including cannabinoid content and certain elements, by reviewing consumer and industry complaints submitted to the Agency and by conducting online surveillance. Products identified for testing included products marketed with "disease claims" and products intended for vulnerable populations, and were marketed as tinctures/oils, capsules/powders, edibles, beverages, and products marketed for pets. Of the twenty-one products that specified how much CBD was present per serving, seven (thirty-three percent) contained CBD within twenty percent of the amount indicated. Of the ten products that did not indicate the amount of CBD included in the product, six contained CBD and four did not. In addition, fifteen of the thirty-one products (forty-eight percent) contained THC. FDA further indicated in the July 8 report that it plans to conduct long-term sampling and has developed a sampling methodology to create a representative, random sample of the current CBD product marketplace. The Agency will favor products with a higher market share.

- On July 22, 2020, FDA announced the availability of its draft guidance for industry, "Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research."[37] The Draft Guidance outlines several key thoughts regarding research and development of cannabis and cannabis-derived drug products. Importantly, the document provides a new method for drug sponsors, investigators, and applicants (developers) to calculate the percent of delta-9 tetrahydrocannabinol (THC) present in botanical raw materials, extracts, and finished products, which is relevant to assess the controlled substance status of the tested material. The 2018 Farm Bill legalized the production of hemp, which is defined as cannabis and derivatives or extracts of cannabis with no more than 0.3 percent THC by dry weight. Any cannabis or cannabis derivative with more than 0.3 percent THC is considered a Schedule I controlled substance ("marihuana") under the Controlled Substances Act (CSA) and subject to the Drug Enforcement Administration's (DEA) authority.

---

[36] For more information on FDA's Sampling Study, *see* Lauren Farruggia and Jonathan Havens, *FDA Sends CBD Enforcement Policy to OMB, Issues Cannabis Clinical Research Draft Guidance, and Submits CBD Testing Report to Congress*, SAUL EWING ARNSTEIN & LEHR LLP CLIENT ALERT (July 24, 2020), https://www.saul.com/node/68341.

[37] U.S. FOOD & DRUG ADMIN., CANNABIS AND CANNABIS-DERIVED COMPOUNDS: QUALITY CONSIDERATIONS FOR CLINICAL RESEARCH GUIDANCE FOR INDUSTRY: DRAFT GUIDANCE FOR INDUSTRY (July 2020), https://www.fda.gov/media/140319/download.

In the Draft Guidance, FDA recommends that developers base the calculation of THC percentage "on the composition of the formulation with the amount of water removed, including any water that may be contained in excipients." This new method of testing, while targeted at drug development, could provide insight into how the Agency may calculate the THC content of consumer CBD products in the future, although that remains to be seen. Testing is crucial early in the development process, according to the Agency, so that developers may "gain insight into the potential control status of their product" from the start. FDA recommends that sponsors and developers consult with DEA regarding the control status of their cannabis materials or products that are under development, should such materials exceed 0.3 percent THC. The Draft Guidance also addresses source material for cannabis drug products, explaining that, while any cannabis meeting the definition of "hemp" under the 2018 Farm Bill is legal, currently, only cannabis above 0.3 percent THC sourced from the National Institute on Drug Abuse (NIDA) Drug Supply Program (DSP) is permitted for clinical research (i.e., even cannabis grown in compliance with the laws and regulations of a state medical cannabis program would not be permitted to support development of a drug product for which FDA approval is sought). While the Agency's statements regarding the importance of research and development of cannabis-derived therapeutics are encouraging, until DEA expands sourcing availability for "marihuana" research, there will be little progress in domestic research and development. DEA is reportedly in the process of allowing additional growers and bulk manufacturers to register with DEA to produce and distribute cannabis for research purposes, but this process has been extremely protracted.

- Finally, and also on July 22, 2020, FDA sent to the White House Office of Management and Budget (OMB) a draft guidance, "Cannabidiol Enforcement Policy."[38] Because the draft guidance is not yet publicly available, we can only speculate about its contents. However, it seems that clarity could finally be coming to the CBD space, presuming OMB clears the guidance and FDA issues it thereafter. It is hard to believe that the Agency will back off completely from its "ingestibles are not permitted" stance. Perhaps the enforcement policy will be claims-focused (e.g., outlining further what would constitute impermissible disease claims). This seems somewhat unlikely, as industry already has a good sense of what FDA will tolerate and what it will not as all enforcement action against CBD products, to date, has centered on very aggressive disease claims. However, if the Agency outlines the same in a formal enforcement discretion policy, it could give more certainty to marketers offering ingestible products bearing anything other than

[38] *See* OMB, OIRA, "Cannabidiol Enforcement Policy; Draft Guidance for Industry; Availability," received July 22, 2020, https://www.reginfo.gov/public/jsp/EO/eoDashboard.myjsp.

disease claims. Less likely is that FDA will lay out specific serving size limits (e.g., unless and until the Agency issues a CBD ingestibles rule, any supplement with 50 mg CBD per serving or less will be subject to enforcement discretion). This also seems unlikely, given the data gaps FDA perceives to exist and thus the lack of support for establishing consumption limits. While some stakeholders think that 50 mg CBD or less per serving might be an appropriate limit, we do not believe the Agency will be that proscriptive in an area that it seems to still be wading its way through. On the product standards front, it is possible that FDA could start to hold ingestible CBD marketers to the Agency's dietary supplement regulations (e.g., good manufacturing practice (GMP) requirements). This is certainly what the supplement industry/trade associations have been pushing for, as it would raise the bar for the industry, push out unsavory firms who are producing unsafe products, and allow marketers to say that they comply with FDA requirements (which would hopefully smooth out the true patchwork of state requirements), among other benefits. However, it is not clear that FDA is prepared to go that far. OMB review time is difficult to predict, in that some guidance documents get reviewed quickly (e.g., less than two months in the case of FDA's cannabis clinical research guidance), whereas others take several months or longer. Generally, we might expect to see a decision from OMB on the enforcement policy somewhere between October and January 2021 (or longer).

NEW NUTRITION FACTS LABEL REQUIREMENT GOES INTO EFFECT FOR LARGEST FIRMS, FDA ISSUES RELATED GUIDANCE DAYS BEFORE DEADLINE

On May 27, 2016, FDA published final rules on the new Nutrition Facts Label (NFL) for packaged foods.[39] Despite rollout delays, the Agency finally seemed poised to move forward with the NFL rules as of late March 2018. However, it was not until December 30, 2019, just two days before the NFL rules were set to go live for firms with annual sales over $10 million, that FDA issued its final NFL guidance aimed at conventional food and dietary supplement manufacturers.[40] Manufacturers with less than $10 million in annual food sales have an additional year to comply.[41] The guidance addresses a number of topics, including: (1) the definition of a single-serving container; (2) reference amounts customarily consumed (RACCs), which are used by companies to determine serving sizes; (3) dual-column labeling, including formatting

[39] 81 Fed. Reg. 33,741, 33,999 (May 27, 2016).

[40] U.S. FOOD & DRUG ADMIN, FOOD LABELING: SERVING SIZES OF FOODS THAT CAN REASONABLY BE CONSUMED AT ONE EATING OCCASION, REFERENCE AMOUNTS CUSTOMARILY CONSUMED, SERVING SIZE-RELATED ISSUES, DUAL-COLUMN LABELING, AND MISCELLANEOUS TOPICS: GUIDANCE FOR INDUSTRY (Dec. 2019) [hereinafter FOOD LABELING GUIDANCE], https://www.fda.gov/media/133699/download.

[41] *Industry Resources on the Changes to the Nutrition Facts Label*, U.S. FOOD & DRUG ADMIN. (current as of September 18, 2020), https://www.fda.gov/food/food-labeling-nutrition/industry-resources-changes-nutrition-facts-label.

issues for products that have limited space for nutrition labeling; and (4) a variety of other issues, such as requirements relating to the labeling of chewing gum and to multi-unit retail food packages.

Per the guidance, a single-serving container is a product that is packaged and sold individually (i.e., that bears an NFL and contains less than 200 percent of the applicable RACC for that product).[42] The entire content of a single-serving container must be labeled as one serving.[43] The Agency provides as an example of a single-serving container a 20-oz bottle of soda.[44] The RACC for carbonated beverages is 12 oz (360 mL); a 20-oz bottle of soda contains approximately 167 percent of the RACC and meets the definition of a single-serving container.[45]

By contrast, products that are packaged and sold individually and that contain at least 200 percent and up to and including 300 percent of the applicable RACC (e.g., a 75-gram bag of chips that is 250 percent of the RACC of 30 grams for chips) must provide an additional column within the NFL that lists the quantitative amounts and percent daily values (DVs) for the entire package, as well as a column listing the quantitative amounts and percent DVs for a serving that is less than the entire package (i.e., the serving size derived from the RACC), unless an exception applies.[46] The first column must list nutrition information based on the serving size for the product, and the second column must list the nutrition information based on the entire contents of the package.[47]

The dual-column labeling requirements also apply to products in discrete units.[48] If a discrete unit weighs at least 200 percent and up to and including 300 percent of the applicable RACC, the serving size will be the amount that approximates the RACC, and the product label must provide dual-column labeling for the discrete unit, unless an exemption applies.[49] The first column would list the nutrition information based on the serving size, while the second column would list the nutrition information for the individual unit.[50]

With regard to dual-column labeling exemptions for small packages, an exemption is available for products that have: (1) a total surface area available to bear labeling of less than 12 square inches; or (2) a total surface area available to bear labeling of 40 or less square inches and the package shape or size cannot accommodate a standard vertical column or tabular display on any label panel. Some other notable exemptions from the requirement include: (1) raw fruits, vegetables, and seafood for which nutrition labeling is provided voluntarily on the product or in advertising, or as is required when claims are made about the product; (2) products that require further preparation (e.g., pancake mix) and for which an additional column of nutrition information for the "as prepared" form of the food is voluntarily provided; (3) products

---

42 FOOD LABELING GUIDANCE, *supra* note 40, at 6.

43 *Id.*

44 *Id.*

45 *Id.*

46 *Id.* at 12.

47 *Id.*

48 *Id.*

49 *Id.*

50 *Id.*

that are commonly consumed in combination with another food (e.g., cereal and milk) and for which an additional column of nutrition information for the combination is voluntarily provided; (4) products for which an additional column of nutrition information for two or more groups for which Reference Daily Intakes (RDIs) are established (e.g., both infants and children less than four years of age) and provided; (5) popcorn products for which an additional column of information per 1 cup popped popcorn is provided; and (6) varied-weight products.[51]

In explaining the reasoning behind the NFL rules, and the guidance, Claudine Kavanaugh, Ph.D., MPH, RD, Director of the Office of Nutrition and Food Labeling in FDA's Center for Food Safety and Applied Nutrition, noted that:

The new Nutrition Facts label has updated serving sizes for many foods. We know that Americans are eating differently, and the amount of calories and nutrients on the label is required to reflect what people actually eat and drink—not a recommendation of what to eat or drink. The new label, including this dual column layout, will drive consumers' attention to the calories and Percent Daily Value of nutrients that they are actually consuming.[52]

Despite the Agency's issuance of draft guidance in November 2018, the timing of the final guidance—so close to the NFL rules' compliance date—could lead to some stress, to say the least. Fortunately, however, FDA announced that it does not plan to take enforcement action until July 1, 2020, focusing in the meantime on working to educate manufacturers that are not in compliance.[53]

---

[51] *Id.* at 13.

[52] *FDA Issues Final Guidance on Serving Sizes, Dual-Column Labeling*, U.S. FOOD & DRUG ADMIN. (Dec. 30, 2019), https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-final-guidance-serving-sizes-dual-column-labeling.

[53] *Id.*