

The Public Health Rationale for Recommended Restrictions on New Tobacco Product Labeling, Advertising, Marketing, and Promotion

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I. Background

Most tobacco use is established in adolescence and age of initiation plays a significant role in the progression from tobacco experimentation to regular use (HHS 2012). It is well established that industry practices, such as tobacco product labeling, advertising, marketing and promotion, substantially impact youth trial and uptake of tobacco product use. Part of FDA’s premarket review under the PMTA pathway is aimed at determining if marketing a new tobacco product would increase or decrease the likelihood that those who do not currently use tobacco products, will start using them.

Firms seeking a marketing order for a new tobacco product not yet on the market may not have robust data on how U.S. consumers will perceive the specific product, including its risks, or the degree to which its labeling, advertising, marketing, and promotion may influence youth perception or appeal to youth. This memo describes FDA’s authorities under the Family Smoking and Tobacco Control Act (Tobacco Control Act) to monitor and restrict tobacco product marketing and related activities in the context of premarket tobacco product application review and authorization. Given FDA’s statutory mandate to protect young people from the dangers of tobacco use and ensure that the marketing of new tobacco products is appropriate for the protection of the public health, the agency can request and review labeling, advertising, marketing, and promotional materials and plans for new tobacco products that have received premarket authorization to ensure that there are no grounds for withdrawing authorization and restrict the marketing of such products as appropriate for the protection of public health. This will help FDA evaluate the potential impact of such materials on the likelihood of initiation and use of the new tobacco products by youth or others and provide the firm and/or the agency an opportunity to prevent or mitigate any related potential harms to the public health.

II. The Food, Drug, and Cosmetic Act, as Amended by the Tobacco Control Act: Congressional Findings and FDA Authorities Related to Tobacco Product Labeling, Advertising, Marketing, and Promotion

The Tobacco Control Act makes clear the harmful influence of tobacco product labeling, advertising, marketing and promotion on youth tobacco use, and the intent of Congress to give FDA the authority to restrict these activities. In the Tobacco Control Act, Congress finds that, “[t]obacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents,” and “[b]ecause past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed.” TCA §2(5) and (6). Thus, Congress concludes, “[c]omprehensive advertising restrictions will have a positive effect on the smoking rates of young people,” and “[r]estrictions on advertising are necessary to prevent unrestricted tobacco advertising from undermining legislation prohibiting access to young people and providing for education about tobacco use.” TCA §2(25) and (26).

These findings are underscored by section 906(d) of the FD&C Act, which grants FDA the authority to “require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if [...] such regulation would be appropriate for the protection of public health,” and section 910(a)(2) of the FD&C Act, which grants FDA the authority to require premarket review and authorization of a new tobacco product before such product may be legally marketed in the United States. Further, as part of premarket application review, FDA may require “information relevant to the subject matter of the application” to assist the agency in determining “whether the marketing of a tobacco product [...] is appropriate for the protection of public health” (section 910(b)(1)(G) and 910(c)(4) of the FD&C Act). In an order authorizing the marketing of a new tobacco product, FDA may also restrict the sale and distribution of the tobacco product to the extent that the sale and distribution of a tobacco product may be restricted under section 906(d) of the FD&C Act. FD&C Act §910(c)(1)(B).

III. Effects of Youth-Exposure to Tobacco Product Labeling, Advertising, Marketing, and Promotion on Youth-Appeal, -Perception, and -Use of Tobacco Products

A. Influence of Tobacco Product Marketing on Youth Tobacco Use, in General

As noted in the FD&C Act, as amended by the Tobacco Control Act, a key consideration in determining whether the marketing of a tobacco product is appropriate for the protection of public health is whether the marketing of the product would increase or decrease the likelihood that those who do not use tobacco products, especially youth, will start using them. In addition to Congress’ findings in the Tobacco Control Act, there is a large body of scientific evidence that documents the potential harm of tobacco product labeling, advertising, marketing and promotion on youth tobacco use.

In one of the first comprehensive reviews on the subject—the National Cancer Institute’s (NCI) 19th monograph, *The Role of the Media in Promoting and Reducing Tobacco Use*—authors conclude that “the total weight of evidence—from multiple types of studies, conducted by investigators from different disciplines, and using data from many countries—demonstrates a causal relationship between tobacco advertising and promotion and increased tobacco use” (NCI 1998). As such, the direct role of tobacco product marketing and related activities in increasing tobacco use in the United States, especially among youth, and the high rates of youth-exposure to tobacco marketing due to its ubiquity, are two key rationales cited by NCI for restricting tobacco product marketing and related activities.

The 2012 Surgeon General’s report, *Preventing Tobacco Use Among Youth and Young Adults*, synthesizes more than 30 years of research on the topic. This report outlines similar findings—tobacco product labeling, advertising, marketing, and promotion influence a wide range of established risk factors for youth tobacco use by shaping attitudes, beliefs, and risk perceptions, and promoting pro-tobacco social and cultural norms. The report states, “there is strong empirical evidence, along with the tobacco industry’s own internal documents and trial testimony, as well as widely accepted principles of advertising and marketing that support the conclusion that tobacco manufacturers’ advertising, marketing, and promotions recruit new users as youth and continue to reinforce use among young adults” (HHS 2012). This evidence is sufficient to conclude that “marketing efforts and promotion by tobacco companies show a consistent dose-response relationship in the initiation and progression of tobacco use among young people” (HHS 2012).

To illustrate these points, the report cites findings of studies that demonstrate “advertising and promotion by the tobacco industry are effective in raising awareness of smoking, increasing brand recognition, and creating favorable beliefs regarding tobacco use. There is strong and consistent evidence that marketing influences adolescent smoking behavior, including selection of brands,

initiation of smoking, and overall consumption of cigarettes” (HHS 2012). Further, “research conducted by the tobacco industry consistently demonstrates that the brand imagery portrayed on packages is particularly influential during youth and young adulthood—the period in which smoking behavior and brand preferences develop,” and “displays of packages in retail outlets, commonly referred to as ‘powerwalls,’ have high visibility among youth and help to establish brand imagery and social norms at an early age” (HHS 2012). “Young people who are more familiar with tobacco advertising can identify specific advertisements, have a favorite tobacco advertisement, or possess cigarette promotional items are more likely to begin smoking than their peers who do not have these characteristics,” and “adolescents who both owned cigarette promotional items and had a favorite cigarette advertisement” were more likely to progress from initiation of smoking to established smoking (HHS 2012).

Research has found that a key tactic of tobacco companies seeking to attract and recruit youth users is to use advertising with aspirational imagery and themes known to resonate with younger audiences, such as independence, popularity, rebelliousness, attractiveness, and being “cool” (HHS 2012). Even tobacco advertising that purportedly targets adult users can have a profound influence on adolescent tobacco use behaviors if it creates positive feelings in youth toward the product; pleasant feelings motivate actions that consumers anticipate will reproduce those feelings (Slovic & Peters 2006). As such, youth are more likely to mimic behavior portrayed as favorable in advertising, such as tobacco use. Furthermore, youth often misjudge the risks and benefits of advertised products based on how they feel about them (Slovic & Peters 2006). If youth feel positively toward a product, they are more likely to perceive it as having lower risks and higher benefits.

In addition, adolescents are “uniquely susceptible to social and environmental influences to use tobacco” given their developmental stage and are heavily influenced by peers, family members, prominent members of their community, celebrities, and other cultural icons and adult role models—especially those they perceive to be popular, attractive, and “cool” (HHS 2012). As such, images of tobacco use in various types of media are “a potentially powerful socializing force among adolescents, in part because they are communicated by people who are identified by youth as media stars,” and “adolescents actively rely on external information as they seek to shape their own identities, often looking to media stars as models of what to wear and what to do” (HHS 2012). These marketing campaigns may be misleading in that they imply positive, pervasive and/or pro-tobacco social norms that are inaccurate or overstated. The misleading impression can be enhanced by failing to disclose a sponsor’s relationship with a company or failing to reveal that the content was not organically generated independently of the sponsoring company. Because youth have a heightened sensitivity to normative influences, sponsored tobacco marketing content may encourage youth uptake of tobacco use (HHS 2012).

B. Influence of Tobacco Product Marketing on Youth Tobacco Use in the Context of Novel Tobacco Products

Much of the research spanning the past few decades has focused on the influence of tobacco product marketing on cigarette smoking in particular; however, companies that sell other types of tobacco products engage in the same labeling, advertising, marketing, and promotional practices used by cigarette companies. “[T]he traditional division of products, brand identities, and marketing between cigarette and smokeless tobacco companies has all but become nonexistent in recent years as major U.S. cigarette companies, including RJR and Altria, have acquired smokeless tobacco companies and have developed new smokeless tobacco products” (HHS 2012). Some of these products are even marketed with popular cigarette brand names (e.g., Camel Snus).

Beyond cigarette-specific marketing, research has found that youth exposed to in-store marketing of e-cigarettes, hookah, cigars, smokeless tobacco, and pipe tobacco were two to three times more likely to use those products as well as to initiate cigarette use (Cruz et al. 2018). Further, research exploring the influence of tobacco marketing on youth use of novel tobacco products, such as e-cigarettes, confirms that exposure and receptivity to tobacco advertising is significantly associated with tobacco initiation among adolescents. The 2016 Surgeon General’s report, *E-cigarette Use Among Youth and Young Adults*, concluded “e-cigarette products are marketed in a wide variety of channels that have broad reach among youth and young adults,” and themes in e-cigarette marketing are “parallel to the themes and techniques that have been found to be appealing to youth and young adults in conventional cigarette advertising and promotion” (HHS 2016).

The report also summarizes the results of several studies looking at the relationship between e-cigarette marketing and youth tobacco use. For example, an analysis of the 2011 National Youth Tobacco Survey (NYTS) found that “adolescents who reported frequent exposure to protobacco advertising at the point of sale and on the Internet (e.g., seeing ads most of the time or always) had significantly higher odds of ever using e-cigarettes, and there was a dose-response association between the number of marketing channels to which they were exposed and ever use” (HHS 2016; Agaku & Ayo-Yusuf 2014). Two analyses of 2014 NYTS data assessing exposure to e-cigarette advertising in different channels (i.e., internet, print, television and movies, retail stores) found that “exposure to each type of e-cigarette marketing was significantly associated with increased likelihood of ever having used and current use of e-cigarettes among middle and high school students. Exposure was also associated with susceptibility to use e-cigarettes among current nonusers. In multivariate models, as the number of channels of e-cigarette marketing exposure increased, the likelihood of use and susceptibility also increased” (HHS 2016; CDC 2016; Mantey et al. 2016). These findings are particularly relevant in the context of more recent NYTS data showing a substantial increase in youth use of e-cigarettes from 2017 to 2018 (Gentzke et al. 2019). This uptick in youth e-cigarette use also contributed significantly to the first increase in overall youth tobacco use in recent years (Gentzke et al. 2019).

Recent studies have also assessed the influence of e-cigarette marketing on youth use of conventional cigarettes. For example, an analysis of data collected between 2013-2015 via the Population Assessment of Tobacco and Health study found youth receptivity was highest for e-cigarette advertising (compared to conventional cigarette, cigar, and smokeless tobacco product advertising), and receptivity to e-cigarette advertising was also associated with initiation of conventional cigarette smoking (Pierce et al. 2018). Another study had similar findings concluding that exposure to any e-cigarette advertising may play a role in teens’ decision to initiate e-cigarette and conventional cigarette use (Padon, Lochbuehler, et al. 2017). These findings further underscore the powerful influence of tobacco product labeling, advertising, marketing, and promotion within and between product types, and the need for marketing restrictions for novel tobacco products.

C. Influence of Digital Tobacco Marketing on Youth Tobacco Use

While all tobacco product labeling, advertising, marketing, and promotion has the potential to significantly influence youth tobacco use, digital¹ labeling, advertising, marketing, and promotion is particularly concerning given that it is transforming traditional marketing practices and is highly targeted to young people. The Pew Research Center reports that a vast majority of teens have access to a home computer or smartphone and nearly half of teens report using the internet “almost constantly” (2018), which means that many youth are constantly being exposed to marketing of a variety of different products, including tobacco products. While there is overwhelming evidence that children, teens, and

¹ For the purposes of this document, here and throughout the document, “digital” includes internet/online and mobile.

young adults are exposed to and influenced by marketing of unhealthy products in traditional media, the internet provides marketers with new, relatively inexpensive channels and tools for disseminating their messages (Dunlap et al. 2016). Research examining online engagement with tobacco marketing among youth found a sizable increase of engagement over time (Soneji, Yang, Knutzen, et al. 2018) and that the number of engagements is associated with tobacco use initiation, frequency of use, and progression to poly-product use (Soneji, Yang, Moran, et al. 2018). According to the 2012 Surgeon General's report, "the techniques of digital marketing are part of sophisticated behavioral targeting in which the marketer collects data on the users' every move (e.g., every click of the mouse, sign-up for a contest, forwarding to a friend) to enable ever more precisely targeted marketing" (HHS 2012). This precision marketing also represents an opportunity to limit youth-exposure to the digital marketing of tobacco products.

Via social media applications, marketers gain access to detailed profiles of users and their friends. Social media has fundamentally altered the marketing landscape by moving young audiences from passive recipients of advertising to active participants in the co-creation and dissemination of marketing messages (Dunlap et al. 2016). Corporate brands leverage the use of social media by adolescents and young adults to target and engage with young audiences (Dunlap et al. 2016). Unlike traditional forms of advertising that target potential customers with ads, companies that join in the "complex network of relations" of social media "befriend" their customers, which is a particularly appealing approach for companies wanting their consumers to express their personality through brand association (Dunlap et al. 2016). "Marketers seek to create 'brand ambassadors,' [i.e., social-media influencers] who promote the product in the context of their online communications, whether or not such promotions are recognized by the users or receivers as marketing. The effect is to blur the distinction between marketing communications and market research" (HHS 2012).

For example, a study examining message content on Twitter concluded that Twitter serves as an important platform for e-cigarette marketing (Chu et al. 2015). Whenever a message posted by an e-cigarette brand is "retweeted" by another user, the message has reached a new network of users. Additional retweets can provide a cascading spread within and outside an original poster's network and cause the message to go viral. This exposure through a retweeting network allows rapid diffusion of messages across groups (Chu et al. 2015). However, Twitter content often reaches unintended audiences, including youth and other vulnerable populations, due to the platform's exponential reach and relatively limited control over what types of people are exposed to specific messages (Chu et al. 2015). With more than 30% of today's youth reporting they use Twitter, marketing and promotion of tobacco products through Twitter can influence youth (Pew Research Center 2018). In addition, a recent study found that sales growth of JUUL was accompanied by a variety of innovative, engaging, and wide-reaching campaigns on social media platforms popular among youth, such as Twitter, Instagram, and YouTube (Huang et al. 2018).

IV. The Public Health Rationale for Requiring Submission of New Tobacco Product Labeling, Advertising, Marketing, and Promotional Materials and Plans and for Placing Restrictions on the Marketing of New Tobacco Products to Limit Youth-Exposure to Such Marketing

A. Purpose of Marketing Requirements and Restrictions for New Tobacco Products, in General

As noted in the introduction, FDA has a statutory mandate to ensure that the marketing of new tobacco products is appropriate for the protection of the public health. FDA's premarket review under the PMTA pathway is aimed, in part, at determining if marketing a new tobacco product would increase or decrease the likelihood that those who do not currently use tobacco products will start using them. Among non-users, youth are a significant population of concern as their current stage of brain

development makes them especially susceptible to nicotine addiction (HHS 2012). Prior sections of this memo have illuminated the powerful impact of tobacco product labeling, advertising, marketing, and promotion on youth-perceptions of tobacco products, youth-appeal of tobacco products, the likelihood of youth initiation and use of tobacco products, even when said marketing is purportedly targeted or designed to appeal to adults. Thus, for FDA to help ensure that the continued marketing of a new tobacco product is appropriate for the protection of public health, it is critical for FDA to conduct ongoing review and evaluation of the product's labeling, advertising, marketing, and promotional materials and plans to assess any possible effects on perceptions, appeal, intentions, and behaviors among intended and unintended audiences, and to place appropriate restrictions on the product's marketing and related activities from the outset to limit youth-exposure to such marketing.

Additionally, requiring a firm that receives marketing authorization for its products to provide labeling, advertising, marketing, and promotional materials and plans in advance of their use on an ongoing basis is not for pre-approval, but will provide FDA timely access to such materials and plans and, if needed, allow FDA to provide advisory comments, including any concerns about their possible impact on youth appeal and tobacco use initiation and on the finding that continued marketing of the products is appropriate for the protection of the public health.

B. Reducing Youth-Appeal of Tobacco Product Marketing

Generally, firms receiving marketing authorization for a new tobacco product should seek to reduce the youth-appeal of the tobacco product's labeling, advertising, marketing, and promotional materials, including avoiding the use of imagery and themes known to resonate with youth, such as aspirational content depicting tobacco use as "cool," attractive, rebellious, and/or risky, or as a means to make one more popular, desirable, or independent (HHS 2012). Other potential strategies for limiting youth-appeal of labeling, advertising, marketing, and promotional materials include focusing marketing content on instructional demonstrations and product comparisons and avoiding bright, bold, cheerful designs and colors, which can influence youths' product choices because these characteristics affect their perception of the products, draw attention to them, and influence purchase decisions (Padon, Mahoney, et al. 2017; Akcay 2012; Lempert & Glantz 2016).

Instead, labeling, advertising, marketing, and promotional materials should be clearly tailored to appeal to adults by using personalization strategies that make the content relevant and meaningful to adult recipients and should depict individuals who are similar to the target audience in terms of attributes, beliefs, and interests, in relatable situations that make it easier for adult viewers to engage with and connect to the advertising (Hawkins et al. 2008; Nielsen 2014). For example, advertising tailored to adult tobacco users would likely use headline and body copy that is relevant only to adults who might be considering switching products; would use models that are obviously older adults (ages 35-54) who look like and/or explicitly state they are tobacco users; and would portray people in realistic situations for tobacco users without making them look highly appealing or aspirational to other non-targeted populations, such as youth.

C. Limiting Youth-Exposure to Tobacco Product Marketing

Given the association between tobacco product marketing and youth initiation of tobacco use detailed in Section III, to help ensure the marketing of the products receiving marketing authorization under the PMTA pathway remains appropriate for the protection of public health, it is critical to limit youth-exposure to the products' marketing, advertising, labeling, and promotion. Placing certain marketing

restrictions² on the newly authorized tobacco products from the outset, such as the media channels through which the firm markets its products, are essential components of limiting youth-exposure, and are thus appropriate for the protection of public health.

1. Restrictions on Paid Digital Tobacco Product Marketing

The rise of digital marketing has changed media consumption habits over the past decade and created an increasingly complex media landscape where it is not yet possible to completely eliminate youth-exposure to tobacco marketing. However, the data sources, methodologies, and technologies used to deliver and track digital media consumption have also evolved, enabling product marketers to create sophisticated, highly targeted digital marketing plans and paid media buys designed to reach their intended audiences based on specific demographics, psychographics, and media passion-points while also limiting reach or “spill” to unintended audiences. Thus, it is possible, efficient, and necessary for firms to take advantage of these technologies to help ensure that tobacco product marketing is targeted to adults and that “spill” to youth audiences is minimal.

For example, paid digital advertising targeting capabilities have evolved such that it is possible, if not standard practice, to target paid advertising using sophisticated data management systems and algorithms connecting individuals to a range of data points, including their demographic characteristics, purchase behaviors, preferences, political opinions, internet search terms, browsing history, interactions with digital content (e.g., liking a social media post, following a specific influencer, sharing a video), digital accounts, connected devices, physical location, and information about other members of their household. Consumers are also increasingly digitizing and sharing detailed information about their personal beliefs, experiences, and behaviors, giving marketers ever-growing capabilities to track and target individuals who meet the exact demographic and psychographic profiles of their ideal consumers. As a result, targeting advertising based on a “digital destination,” such as placing advertising on a specific website, is becoming largely obsolete and economically inefficient in comparison to targeting advertising based on specific digital profiles connected to actual consumers who can thus be reached in almost any digital location and time (IAB 2018).

This is especially significant when considering the need to limit youth-exposure to tobacco marketing appearing in the digital environment, which is exponentially more vast, ever-changing, and difficult to categorize than more traditional media channels like broadcast television and radio and print, making it difficult to accurately determine the audience composition of a specific digital property (i.e., what percent of visitors to a specific website are within a certain age-range), or even assess where one digital property ends and another begins. Fortunately, paid digital advertising targeting capabilities offer tobacco marketers the ability to target adults who meet specific age criteria through the use of first- and/or second-party age-verified data (see table) on any digital property accepting paid tobacco advertising, while also restricting youth-access to such advertising. Marketers can also layer on additional demographic and psychographic data (e.g., tobacco product purchase behaviors) to further enhance the efficiency of their paid digital media buys.³

² For the purposes of this document, this section focuses on restrictions related to digital tobacco product marketing. Considerations for other types of marketing restrictions may be addressed in the future, and the contents of this document should not be viewed as an exhaustive list.

³ In addition to first- and second-party age-verified data, firms can use data obtained from data aggregators who categorize consumers based on trackable activities and inferred interests (e.g., internet search terms, video interactions, browsing history, purchasing behaviors) to create demographic and psychographic profiles to enhance first- and second-party age-verified audience targeting data. However, such data is not considered age-verified and should only be used in combination with first- and/or second-party age-verified data.

Table. Definitions of first- and second-party age-verified data

First-party age-verified data	Data owned by a firm (e.g., a firm’s customer registration data collected via site traffic to the firm’s company-owned website; data the firm uses in direct marketing to its adult smoking customers) that the firm has age-verified through independent, competent, and reliable data sources.
Second-party age-verified data	First-party data owned and age-verified by another competent and reliable entity (e.g., another company’s first-party user registration data) to which a firm has access. This data must be age-verified by the second party and not through data aggregators.

Using targeting through the use of first- and/or second-party age-verified data (see table) does not mean that a firm will not be able to advertise at all in certain digital platforms, for example on certain websites that do not have age-restriction measures in place. Rather, even if a website does not have its own first-party age-verified data, tobacco advertising could still show up on that site. For example, if an adult that a tobacco marketer has age- and identity-verified as meeting the federal minimum legal age to purchase tobacco products through independent, competent, and reliable data sources visits TeenVogue.com, that adult could be delivered a tobacco ad on the site using the marketer’s first-party age-verified targeting data (regardless of whether TeenVogue.com has its own first-party age-verified data to share with the tobacco marketer), but an age-verified teen on TeenVogue.com would not be delivered the same tobacco ad as a result of this targeting. Therefore, through the use of targeting data, different individuals can see different ads when visiting the same website at the same time. This allows for a highly targeted approach to tobacco advertising delivery, which can help ensure that youth exposure is minimized, while at the same time not restricting access to adults.

2. Restrictions on Tobacco Product Social Media Marketing and the Use of Influencers, Bloggers, Brand Ambassadors, etc.

Although paid digital advertising can be effectively targeted using first- and second-party age-verified data to reach adults, there are other types of digital marketing cannot be targeted using this approach. For example, product-branded social media accounts essentially operate as both mini websites and “free” advertising channels offering a range of effective means of directly reaching and engaging consumers. In fact, “the ability to influence a large number of individuals, the minimal effort required to make influence attempts, and the flexibility to deploy a variety of influence strategies through information technologies are a potent combination making influence in online social networks considerably more compelling and pervasive than in conventional interpersonal interactions,” highlighting the need for close scrutiny of these methods (Subramani & Rajagopalan 2003). Further, one of the most effective digital marketing practices today—especially among youth who are particularly susceptible to social influences—is the use of “organic” depictions of tobacco use and endorsements of tobacco products by cultural icons and other influencers through their own social media accounts (HHS 2012).

Thus, as part of ensuring digital media plans and buys for tobacco products are highly targeted to adults while limiting spill to youth, it is critical to mitigate against the incredible reach and influence of social media, including “organic” influencer promotion. Currently, there are no universal age-restriction controls on social media platforms and some do not offer any age-restriction options; however, many social media platforms are beginning to offer branded-account owners the option to age-restrict some

or all of their account pages, followers, and content, including even specific posts, photos, videos, events, etc. These options still face a few additional limitations; for example, most social media platforms allow users to establish their own account profile settings, including self-reported age, and users are not age- or identity-verified. However, users are increasingly prompted to “link” digital profiles and accounts (e.g., option to sign-up for a new account using an existing email account or social media account), increasing the likelihood of more accurate self-reporting.

As part of these restrictions, firms must ensure that their own social media accounts as well as those of any influencers promoting a tobacco product on a firm’s behalf use the available age-restriction controls to restrict youth access to any product promotion disseminated through social media accounts. Firms must also ensure the disclosure to consumers or viewers, via the use of statements such as “sponsored by [firm name],” of any relationships between the firm and entities that creating labeling for, advertise, marketing and/or promote the product on the firm’s behalf to help prevent misleading marketing, which is especially likely to influence youth.

V. Proposed Marketing Restrictions in PMTA Authorization Orders

In this context, FDA should consider including detailed marketing restrictions and requirements, in addition to other requirements, for any new tobacco product receiving market authorization under sections 910(c)(1)(B) and 910(f) of the FD&C Act. FDA should determine such marketing restrictions and requirements on a case-by-case basis when issuing an order that the marketing of a tobacco product is appropriate for the protection of public health. Information that should be considered in these determinations includes, but is not limited to, information submitted to FDA by a firm seeking pre-market tobacco authorization regarding the firm’s intended labeling, advertising, marketing, and promotion of the products; use of industry practices known to substantially impact youth trial and uptake of tobacco product use; new and emerging technologies, media, and marketing practices; and existing applicable laws and legal agreements affecting the sales, distribution, marketing, advertising, labeling, and/or promotion of certain tobacco products.

Generally, firms seeking marketing authorization for new tobacco products should seek to limit youth-exposure to the products’ labeling, advertising, marketing, and promotion. Restrictions in a marketing order should be aimed at the following with respect to advertising and marketing plans, including strategic creative briefs and paid media plans, by channel and by product:

- Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys;
- Targeting of specific adult audiences by age-range(s), including young adults, ages 18-24, and other demographic and/or psychographic characteristics that reflect the intended target audience;
- Actions taken to restrict youth-access and limit youth-exposure to the products’ labeling, advertising, marketing, and/or promotion;
- Use of owned, earned, shared, and/or paid social media to create labeling for, advertise, market, and/or promote the products;
- Use of partners, influencers, bloggers, and/or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
- Consumer engagements, including events at which the products were demonstrated; and/or
- Use of earned media and/or public-relations outreach to create labeling for, advertise, market, and/or promote the products.

Firms should establish, maintain, and monitor use of independent age- and identity-verification service(s) that compare customer information against independent, competent, and reliable data sources, such as public records, to prevent **digital sales** of the products to individuals who are under the federal minimum legal age to purchase tobacco products.

Firms should establish, maintain, and monitor use of independent age- and identity-verification service(s) that compare consumer information against independent, competent, and reliable data sources, such as public records, at the first point of access to any **owned digital properties** (e.g., the firm's company-owned, consumer-directed, product-branded website(s) and/or mobile applications), to restrict access to any of the products' labeling, advertising, marketing, and/or promotion appearing in such properties to only individuals who are at least of federal minimum legal age to purchase tobacco products.

Firms should establish, maintain, and monitor use of the available site-, platform- and content- (e.g., post, video) specific age-restriction controls (e.g., age-restrict an entire product-branded account and all associated content disseminated through such account; ensure age-restriction of a specific video disseminated by an influencer promoting the products on the firm's behalf through the influencer's account), at the first point of access to any **shared digital properties** (e.g., the firm's product-branded social media accounts, pages and associated content; content promoting the products on the firm's behalf disseminated through another entity's social media accounts), to restrict access to any of the products' labeling, advertising, marketing, and/or promotion appearing in such properties to only individuals who are at least of federal minimum legal age to purchase tobacco products.

Firms should establish, maintain, and monitor use of competent and reliable data sources, methodologies, and technologies to precisely target delivery of any of the products' labeling, advertising, marketing, and/or promotion appearing in **paid digital media** (e.g., paid digital banner advertisements for the product(s) running on another company's website; paid advertising for the product(s) running in social media; paid distribution of influencer content), to restrict access to such labeling, advertising, marketing, and/or promotion to only individuals who are at least of federal minimum legal age to purchase tobacco products. Such targeting must use only first- and/or second-party age-verified data (see table). Firms should restrict advertising practices that are not and/or cannot be targeted using such data (e.g., tactics like "Run-of-Site," "homepage takeovers," "splashy buys").

Firms should establish, maintain, and monitor use of competent and reliable data sources, methodologies, and technologies (e.g., using an embedded tracking pixel in all digital advertising) to **track and measure actual delivery of all advertising impressions**, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic location), including a breakout by age-group (i.e., adults, ages 25+; young adults, ages 18-24; and youth, ages 12-17 and ages 11 and under). Such monitoring should require real-time digital media tracking, and identifying, correcting, and preventing delivery of advertising impressions to youth, ages 17 and under. Such monitoring also should require post-launch delivery verification reports be submitted to the firm from an accredited source (e.g., Media Ratings Council).

Firms should **disclose to consumers or viewers any relationships between the firm and entities** that create labeling for, advertise, market, and/or promote the products, on the firm's behalf or at the firm's direction, via the use of statements such as "sponsored by [firm name]" in any such labeling, advertising, marketing, and/or promotional materials.

It is vital to the continued protection of public health that FDA take these and other marketing-related considerations seriously when evaluating marketing plans to ensure they are sufficiently targeted to limit youth-exposure to tobacco product labeling, advertising, marketing, and promotion. The evaluation

of these marketing plans, including evaluation of their potential impact on youth tobacco use, will help FDA determine whether the marketing, and continued marketing, of the products is appropriate for the protection of the public health.

VI. Conclusion

Given the level of evidence indicating the direct and powerful impact of tobacco marketing on youth tobacco use, and FDA's statutory mandate to protect young people from the dangers of tobacco use, it is both reasonable and critical for firms to submit planned labeling, advertising, marketing, and promotional materials and plans for new tobacco products that are seeking or have received premarket authorization, and for FDA to place restrictions on the marketing of such products. This important safeguard will help FDA ensure, on an ongoing basis, that the continued marketing of new tobacco products remains appropriate for the protection of public health.

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