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Legal Memorandum

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# For First Time, FDA Authorizes Marketing of an E-Cigarette Product

In a first-of-its-kind [decision](https://www.fda.gov/media/153010/download) (the “Authorization”), the FDA has officially [authorized](https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-e-cigarette-products-marking-first-authorization-its-kind-agency) the marketing of an electronic nicotine delivery system (“ENDS”) product (in this case, what’s often colloquially known as an “e-cigarette”) and two accompanying tobacco-flavored e-liquid pods. Note that the FDA’s action is very narrow; the Authorization applies **only** to the specific ENDS system and two e-liquid pods that were the subject of the FDA’s decision, and the Authorization is, to-date, the lone outlier among the [flood of FDA decisions](https://www.fda.gov/news-events/press-announcements/fda-makes-significant-progress-science-based-public-health-application-review-taking-action-over-90) over the last several months that have collectively ordered nearly one million flavored “ENDS” products off the marketplace. Indeed, the FDA has announced that one of its “highest enforcement priorities” going forward will be taking action against any ENDS products that remain on the market unlawfully.

Importantly, although the FDA’s Authorization is the first to authorize the marketing of an e-cigarette, as far as ENDS “flavors” go, the Authorization only applies to the two specific “tobacco-flavored” e-liquid pods discussed therein. The FDA has thus far consistently denied authorization applications for ENDS products with flavors other than tobacco—such as fruit/candy/mint, etc.—in light of the “alarming levels of youth use of such products.”

The FDA has also recently demonstrated that it will enforce the removal of unauthorized, flavored ENDS products from the marketplace—just a few months ago, for example, the FDA issued a [warning](https://www.fda.gov/news-events/press-announcements/fda-brief-fda-warns-firm-over-15-million-products-listed-fda-remove-unauthorized-e-cigarette) to a company with more than 15 million tobacco products listed with the FDA, advising the company that its ENDS products “cannot be sold or distributed in the U.S.”

As an additional wrinkle, many applications for approval to market and sell ENDS products—flavored and otherwise—remain pending with the FDA, including an application submitted by the largest e-cigarette provider in the U.S. by market share, Juul. It therefore still remains to be seen just how many ENDS products will ultimately obtain FDA authorization, particularly now that at least one application for such products has been granted.

For now, broadcasters should be aware of the potential consequences that could result from the FDA’s recent actions—both the Authorization on the one hand, and the FDA’s continued denial of the overwhelming majority of applications related to ENDS products on the other. It is possible that the ENDS advertising category may ultimately experience growth if/when more companies obtain FDA approval to market their products. It is also possible that some advertisers (e.g., local vape shops) may well misconstrue the FDA’s narrow Authorization as permitting more marketing activity than is actually the case, and broadcasters may find themselves having to respond to advertiser requests and comments along those lines. We’d also note, specifically, that the FDA’s Authorization imposes stringent requirements on marketing the three approved ENDS products in broadcast television and radio advertising, with the aim of ensuring that advertisements do not target youth audiences. Although those requirements apply to the manufacturer of the ENDS products—rather than broadcasters themselves—stations should nonetheless be aware of those marketing requirements so that they may calibrate risk and business decisions accordingly.

We’ll continue to monitor this issue for regulatory and marketplace developments.

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# FCC Seeks Comment on Whether to Mandate Broadcaster Participation in Disaster Information Reporting System

In a recent [Notice of Proposed Rulemaking](https://docs.fcc.gov/public/attachments/FCC-21-99A1.pdf) (the “NPRM”) the FCC announced that it is seeking comment on numerous issues related to the reliability and resiliency of communications networks during emergencies, including whether the Commission should expand and/or mandate participation in several of its disaster response programs. The NPRM is especially timely in light of the emergencies recently caused by Hurricane Ida. For the most part, the NPRM discusses non-broadcast issues related to the Commission’s Wireless Network Resiliency Cooperative Framework (the “Framework”), Disaster Information Reporting System (“DIRS”), and Network Outage Reporting System (“NORS”).

Broadcasters, however, will want to take note of one particular proposal advanced in the NPRM: whether broadcasters (among others) should be required to participate in DIRS going forward.

*Background*. Broadcasters are already well acquainted with multiple aspects of the FCC’s rules relating to emergencies, such as those governing the Emergency Alert System (“EAS”) and, for television broadcasters, the FCC’s emergency access rules (among others). But broadcasters may not have had experience with some of the Commission’s other emergency response systems, such as the Framework and DIRS.

The Framework is currently a *voluntary* agreement among wireless providers to provide mutual aid during a disaster. While the Framework’s scope is primarily focused on wireless communications, many of its goals are broadly applicable to all types of communications entities: providing for reasonable roaming arrangements during disasters; fostering mutual aid during emergencies; enhancing municipal preparedness and restoration; increasing consumer readiness; and improving public awareness of service and restoration status.

DIRS is a web-based system the FCC developed and deployed in the wake Hurricane Katrina to provide broadcasters (and others) with the ability to report communications infrastructure status and situational awareness information during and after times of crisis and disaster. Although both the FCC and the NAB have consistently encouraged stations to register with DIRS, participation in the system currently remains voluntary.

*Comments Requested*. The NPRM seeks comment on whether to expand the applicable scope of both the Framework and DIRS for communications industry groups. The NPRM discusses the possibility of including broadcasters in the Framework in generally voluntary terms (albeit with oblique suggestions that mandatory obligations could ultimately be adopted both for wireless providers and for others).

Of potentially greater significance to broadcasters is the NPRM’s discussion of DIRS; the NPRM expressly tees up for comment whether to “consider **requiring** . . . TV and radio broadcasters . . . to report their infrastructure status information in DIRS when the Commission activates DIRS in geographic areas in which they broadcast or otherwise provide service.” The NPRM acknowledges that adopting such a mandatory filing requirement would impose “additional burdens” on broadcasters, particularly given that DIRS reports are filed in the midst of disasters and other emergencies (when broadcasters are quite busy reporting on such disasters and emergencies!). Accordingly, the NPRM seeks comment on the costs and benefits associated with any hypothetical addition of mandatory DIRS reporting, as well as the FCC’s legal authority to impose such reporting and how the FCC should enforce any failure to file DIRS information if such a mandate is adopted.

Comments will be due 30 days after the NPRM is published in the Federal Register, with reply comments due 60 days after publication. We currently believe it is likely that various broadcast industry groups will file comments regarding the issues noted above. We will continue to monitor this issue.

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*Tim Nelson, Editor*

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