FDA Scrutiny Around ENDS Products

Episode 3 – November 1, 2018

Featuring: *Darshan Kulkarni, Vice President, Regulatory Strategy and Policy; and Evan Richardson, Director, Regulatory Services*

Transcript

Intro: This is Synchrocast brought to you by Synchrogenix regulatory and communications strategy, science and solutions.

Darshan Kulkarni: This is Darshan Kulkarni. I am Vice President of Regulatory Strategy and Policy here at Synchrogenix. Evan, do you want to introduce yourself?

Evan Richardson: Yeah. Sure, so my name is Evan Richardson. I'm Director of Regulatory Services here at Synchrogenix. I oversee our team of folks who prepare regulatory submissions and, specifically, I oversee the work we do in preparing submissions to the Center for Tobacco Products.

Darshan: Great, so you are the perfect person to ask this question. Evan, as you know, the FDA has been in the news recently. They have been talking and connecting and commenting on E-cigarettes. Do you want to talk a little bit about what's been going on?

Evan: Yeah, absolutely, so I think FDA has really been cracking down in two main areas recently. The first is use of electronic nicotine delivery system, ENDS products, by minors, and also on companies that may be selling devices that were not actually on the market before the cutoff date of August, 2016. FDA actually has a big concern about E-cigarettes, vaping. There's a lot of data that suggest that youth use of those products is increasing dramatically, and there's a lot of concern about that for the health risks, for the nicotine addiction that can come from that, and also just from the bigger regulatory standpoint of fairness across the board.

There was a deadline in August of 2016. Only devices that had been on the market prior to that date could continue to be sold without a marketing order from FDA. There's some evidence out there to suggest that there are companies that are selling devices that were introduced to the market after that, so they're cracking down on that right now as well.

Darshan: As you see it, what is the impact going to be as the FDA continues? I know the FDA, for example, has identified some companies of special interest, and then they've also identified... they sent out, I believe it was 40 different letters. I forget the number, but it was several different letters. Do you want to talk a little bit about that as well?

Evan: Yeah, so FDA sent out quite a few letters from and to five manufacturers specifically requesting information on what those manufacturers are currently doing and what they will be doing in the future to limit the access and use of their products by minors. Particularly I think FDA has a lot of concern around the flavors that are prevalent in these ENDS products, and so they sent those letters to the manufacturers, the top five manufacturers that hold the majority of the market share in the United States right now.

Again, they're very focused on those flavors that are used. There's evidence out there that suggests that flavors can make these products more appealing to minors, and so that's one area that FDA is focusing a lot on, but I think they're just holistically interested in all aspects of these products, and what might make them have appeal to minors, and what can be done to prevent that.

FDA does see value in ENDS products as an alternative to smoking cigarettes, and so they recognize that there's value in these products being available to help adults stop smoking combustible cigarettes and move to a less harmful product, but they are, at the same time, very concerned about minors who don't smoke at all taking up these products and beginning to use them, and what potential problems that can cause down the road.

Darshan: I think that's a really interesting phrasing that you had there, which is that the FDA definitely sees value in these products. However, I noticed that you were careful in how you phrased that in that you don't see this necessarily as a modified risk product, do you?

Evan: Again, the approval as a modified risk product is a very specific category where it allows a modified risk marketing order, allows a company to make specific claims in their advertising or product labeling that a product is less harmful than other products like combustible cigarettes. I think in the ENDS space right now, the majority of companies that are seeking marketing orders from CTP are going through the Premarket Tobacco Application, PMTA, pathway, where they're not necessarily seeking approval to market the products as safer or less risky. That's a distinction worth noting. That said, independent of any marketing orders or specific statements from FDA, I think there's a lot of information in the public domain that definitely makes the case that a ENDS product, vaping, is less harmful to a user than smoking combustible cigarettes.

Darshan: This is great. Obviously, Evan, I assume you're keeping a close watch on these types of discussions. Is there anything you would want companies who are in this space to be aware of? Does that in any way change whether it's the FDA's focus or whether it is... Would you say it's fair to say that the FDA is not veering off of marketing to minors, therefore the conversation that Synchrogenix has has always been in the context of appropriate use and to adults who actually are, who can make their own decisions, but it would, in all situations, not be violative of targeting minors? Can you talk a little bit

about what companies should be looking out for, and what they should be considering, and how they should achieve these goals?

Evan: Sure. I think especially in light of the recent scrutiny from FDA about the use of these products by minors, companies need to, number one, take this very seriously. FDA has a lot of power and can order these products removed from the market. Such an order from FDA can be devastating to a company, so they need to take these enforcement actions coming from the agency seriously. They need to take the public statements from the agency very seriously. I think our advice to these kind of companies is, you really need to have a well thought out, data supported plan to address the concerns of the agency. FDA is a data driven agency. They make their decisions based on data about the safety and efficacy of drugs, about the risks that come with tobacco products, so having data to back up how you respond to FDA, I think, is going to be essential as a long-term strategy.

FDA's obviously focused a lot on flavorings. I think that's absolutely an area that companies have to pay attention to, but I would warn them to not just solely focus on flavors as the, if we just make changes to our flavor lineup, then that's going to make FDA happy. I think you need to look at things like the form factor of your device. Is it of a form factor that makes it more appealing to youth than other devices? Is it small enough that it lends itself for minors to be able to easily hide such a device from their parents, for example? I think that is a consideration, just the nature of the device itself.

You also need to think about things like your marketing and promotional campaigns. How are they, what is it about them that may be attracting minors unintentionally? Also need to think about the end of the supply chain, the retailers that are selling these devices. Is there more that these companies can be doing to provide oversight of that sales process? Is there more that they can be doing to protect their brand and their reputation by restricting sales, for example, to retailers who have a history of selling to minors?

Companies really need to take a holistic approach, and look at this issue from a lot of different angles to make sure that they are appropriately addressing those concerns.

Darshan: This was great, Evan. Now if someone wants to contact you for more information, can you talk about how they can do that?

Evan: Yeah, absolutely. Please check out the Synchrogenix website. We've got some information on there specific to the services we offer in the tobacco space, which include preparing and submitting applications and information to FDA on your behalf. That includes helping you write documents that comprise those applications, absolutely helping companies come up with strategies to prepare those applications to respond to FDA warning letters, and all those kind of things. Those are all things we can do. We got

more information about that on the Synchrogenix website. Also you can reach out to us there via the contact information available.

Darshan: Great. Thanks again, Evan.

Evan: You're welcome. Thank you.

Closing: Thanks for listening. For more information, visit us at synchrogenix.com.