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New FDA Database To Aid Generic-Drug Makers' Decisions

By **Ryan Davis**

Law360 (June 21, 2019, 10:23 PM EDT) -- The U.S. Food and Drug Administration's expansion of a database about applications for approval of generic drugs should help generics makers decide which products to pursue by providing a clearer picture of the competition they could face, attorneys say.

The FDA said Tuesday that it was expanding the database to provide more information related to the 180-day period of market exclusivity available to the first applicants for a generic drug. It will include the status of the agency's decisions on whether to grant exclusivity to any applicants and the number of potential first applicants that could get exclusivity.

The FDA said in a statement that it is "striving to provide the industry with greater transparency in order to provide greater certainty around timing of market entry and empower more informed decisions on how to prioritize their resources."

The generic-drug industry has been asking the FDA to provide more information about the exclusivity period for years, but the agency has always declined, citing the confidentiality of the Abbreviated New Drug Application process, so the expansion comes as welcome news, said Rebecca Dandeker, a partner at Morgan Lewis & Bockius LLP.

"This helps the day-to-day people in the regulatory affairs departments who are having to move their resources in order to prioritize different ANDAs that are at different stages in the process of either being developed or being approved," she said.

Before this update, there was no way for generics makers to know how many other ANDA applicants could potentially have 180-day exclusivity, which can be a crucial factor in whether a company decides to pursue a new generic product, said Jeffrey Gargano, also a partner at Morgan Lewis.

"I think the biggest impact of this new statement is going to be the information it provides to generic companies so they have a better idea of the marketing landscape, the regulatory landscape and the competitive landscape, so they're in a better position to make business decisions," he said.

The 180-day exclusivity period is important because being the only generic on the market is seen as a major advantage. Several generics makers may qualify for exclusivity, and by being on the market first, they can make arrangements with distributors and insurers that later entrants may not be able to replicate.

With the database, generics makers could see that there are four companies that potentially have exclusivity and will be "in the market for up to six months ahead of you, making all those business deals and cutting you out of the market," Dandeker said. "A lot of times, companies will say, 'I don't need to be fifth one. That's not going to make me any money. I'll just get out.'"

That information may also come into play in patent litigation, where a company making the brand-name drug may accuse numerous generics makers of infringement. If there are seven defendants in a case and one of them can see that four others potentially have exclusivity, it may decide that it's not worth fighting the suit, Gargano said.

"You may make the decision to settle that litigation early, let those companies that have the potential for 180 days of exclusivity to battle the litigation out, and move on to something that is a better investment for your company," he said.

While knowing how many ANDA applications could potentially have 180-day exclusivity is important, it's not the only factor generics makers consider when deciding whether to pursue a product, said Suchira Ghosh of Axinn Veltrop & Harkrider LLP. The expanded database won't provide other information that could be helpful, such as the total number of ANDAs that have been filed, she noted.

"The transparency that this revised spreadsheet is offering is a step in the right direction," she said. "I generally think the agency needs to be more transparent as opposed to less transparent. That said, I think that some of the benefits that FDA is touting are a bit overstated."

The database will only note how many other applicants could potentially have exclusivity, but there may also be several other ANDAs that have been filed that wouldn't have exclusivity. That information would be valuable to generics makers in deciding whether to pursue a product, but it won't appear in the database, Ghosh said.

"So this doesn't give us the full landscape of what generic-drug competition may be shaping up to be for a particular product. So you have to look at it through that lens," she said.

The new information provided by the FDA could shed light on concerns raised by lawmakers that some generics companies are abusing the 180-day exclusivity period by delaying their entry in the market, the point at which the exclusivity period begins, for anticompetitive reasons possibly related to a settlement with the branded company.

Some members of Congress have introduced legislation intended to curb that practice, which is referred to as "parking" of exclusivity. The database will now show when the first filer's ANDA was approved and when it first commercially marketed its product, and if there is a long delay, it could indicate gamesmanship.

While the FDA largely framed the announcement as a way to help generics makers make business decisions, it came with an implicit warning, Dandeker said.

The announcement suggests that "you better not be parking your 180-day exclusivity because now it might become more obvious to everyone in the public," she said. "Now you're going to get bad press possibly. You'll get people calling you out for it, and the [Federal Trade Commission] might look at the issue."

The FDA database could also shed light on the issue by indicating when it has decided that an ANDA filer has forfeited exclusivity for anticompetitive behavior or failure to get approval for its product. That information, particularly if it is accompanied by the actual FDA decisions, could help the industry, and lawmakers considering expanding forfeiture rules to discourage parking, understand what is happening, Ghosh said.

The FDA said it will provide additional information about its forfeiture decisions going forward.

"I think we would end up with so much data that we could actually make some smart analyses about how 180-day exclusivity actually operates," Ghosh said.

"I frankly would like to see that happen before Congress goes in with a carving knife and and starts carving up and revising the 180-day exclusivity forfeiture provisions," she said.

The rules under which the FDA decides to grant exclusivity or deem it to be forfeited are "very arcane and opaque," making it difficult to tell how the agency will decide in any given case, Dandeker said.

"So any kind of 180-day exclusivity information that FDA is willing to release is going to be embraced by the industry to help them understand the policies that FDA is working with," she said.

The FDA's announcement, framed as an effort to help generics companies, is something of a change for the agency. It had tended to be more objective and not speak favorably about one part of the pharmaceutical industry, but that started to change under former FDA Commissioner Scott Gottlieb, who left office this spring, and is continuing with the new database.

"I think this is going to help get more generics into the market in more timely fashion," Gargano said.

He noted that the FDA's view is in line with recent statements by government officials and many bills introduced in Congress aimed at promoting generic drugs.

"It's all aligned to address what I think everyone in the country recognizes is a big problem, and that's the cost of drugs," he said.

--Editing by Jill Coffey and Michael Watanabe.