

FTC Spoke, Kaleo and Impax Listened: Orange Book Patent Delistings Begin

A photograph of a modern building with a curved glass facade, showing multiple floors and windows, set against a light blue sky.

1 MIN READ

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By: Ross E. Blau

As discussed [last month](#), the FTC sent letters to 10 pharmaceutical companies, asserting that their listing of over 100 patents in FDA's Orange Book for a variety of products was improper. Shortly thereafter, the FTC began using the administrative process with FDA to challenge these patent listings, and all of the companies had until [December 16, 2023](#) to respond.

It appears that prior to this deadline at least two companies – Impax Labs and Kaleo, Inc. – may have felt pressure to reconsider their patent listings.

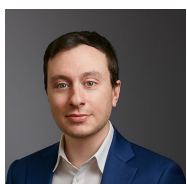
Specifically, Impax [delisted](#) both of its patents directed to Adrenaclick, the same patents that the FTC had noticed in its [November 7, 2023 letter](#). There are currently no approved generic applicants for Adrenaclick, and no additional patents directed to Adrenaclick in the Orange Book. Similarly, Kaleo [delisted](#) eight patents directed to AUVI-Q, the same patents that the FTC had noticed in [its letter to Kaleo](#). Given that the Orange Book lists more than twenty patents for AUVI-Q, it seems that any potential generic applicant still has quite the battle ahead.

It will be interesting to continue to monitor for any further patent delistings, particularly with the December 16, 2023 deadline coming up. Time will tell whether the FTC will take any further action against those companies that don't follow Kaleo and Impax's paths. And, it remains to be

seen whether we can expect further fallout in private litigation from FTC's recent, more aggressive actions in this area.



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