

No Voluntary Delistings or Disputes in FDA's Orange Book Update

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

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FTC recently placed improper Orange Book patent listings squarely in its crosshairs. In its [September 2023 policy statement](#), FTC announced that it would “scrutinize improper Orange Book listings” and “use its full legal authority” to “tak[e] actions against companies and individuals that improperly list patents in the Orange Book that do not meet the statutory listing criteria.” Then, just last week, 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 is improper, in addition to notifying FDA of what it believed were [improper listings](#).

Despite FTC’s more aggressive posture on patent listings, it is noteworthy that companies within the industry have not yet availed themselves of FDA’s patent listing dispute procedure. In fact, just last week, FDA updated its [Patent Listing Disputes list](#), and it contains no updates on patent listing disputes, despite FTC’s policy statement being issued nearly two months ago. The FTC’s recently announced use of this regulatory delisting process will likely be added to an upcoming version of FDA’s Patent Listing Disputes list. Regardless, the lack of current industry interest may be due to the fact that FDA’s patent listing dispute procedure lacks teeth as opposed to any beliefs that current patent listings are accurate.

FDA also released the [October 2023 cumulative supplement to the Orange Book](#) last week, and it shows that no companies have deleted or delisted their patents from the Orange Book, despite FTC’s policy statement. It’s possible that the industry didn’t believe that FTC would

quickly take action on its policy statement, that companies largely believe that all of their patent listings are accurate, or that drugmakers recognize that any resolution of contested patent listings through an administrative or judicial action will take time.

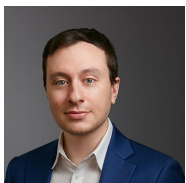
In any event, it will be interesting to continue to monitor the activity at FDA and by FTC. Time will tell whether FTC's actions result in any patent delistings or changes in the Orange Book.



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