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THE LATEST: FTC Submits Comment on FDA Guidance Aimed at Deterring Abuse of Citizen Petition Process

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The Federal Trade Commission (FTC) submitted comments supporting the Food and Drug Administration's (FDA) guidance for assessing whether a pharmaceutical company petitioner is misusing the citizen petition process to delay approval of a competing drug.

McDermott Will & Emery

Article By Gregory E. Heltzer
William DiazJonathan Ende
McDermott Will & EmeryAntitrust Alert

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WHAT HAPPENED:

- The FDA released revised draft guidance intended to discourage pharmaceutical companies from gaming the citizen petition process.
- The FTC expressed approval of the considerations the FDA will use to determine whether a petition was submitted to delay or inhibit competition.
- The considerations the FDA will use include:
    - The petition was submitted unreasonably long after the petitioner learned or knew about the relevant information;
    - The petitioner submitted multiple and/or serial petitions;
    - The petition was submitted close to the expiration date of a known patent or exclusivity;
    - The petition's scientific positions were unsupported by data or information;
    - The petition was the same or substantially similar to a prior petition to which the FDA had already substantively responded;
    - The petitioner had not commented during other opportunities for input;
    - The petition requested a standard more onerous or rigorous than the standard applicable to the petitioner's drug product; and
    - Other relevant considerations, including the petitioner's history with the FDA.

WHAT THIS MEANS:

- Each of the FTC commissioners testified during Senate confirmation hearings that scrutinizing health care and pharmaceutical companies would remain a top priority of the Commission.
- The FTC's support of the FDA guidance appears to be part of a broader agenda to actively pursue sham petitions and discourage attempted abuses that seek to use Noerr-Pennington immunity as a shield in an administrative setting.
    - In 2017, the FTC filed a lawsuit in federal court alleging that Shire ViroPharma Inc. (Shire) violated antitrust laws through repeated use of sham petitioning.

- Though the district court dismissed the FTC's complaint, the FTC has lodged an appeal and appears committed to reining in alleged abuses of the citizen petition process.
- Going forward, citizen petitions are likely to face even more scrutiny. Under the revised draft guidance, once the FDA determines that a petition was submitted primarily to delay competition, it will refer that determination to the FTC. Potentially anticompetitive petitions will now face two rounds of review by federal regulators.