Other citizen petitions remaining in the pool ask that the FDA direct a generic applicant to refile its application in a different form, changing it from an ANDA (the category for generic applications that reference an existing drug) to a 505(b)(2) (the category for generic applications that reference an existing drug but differ slightly in formulation, dosage, treatment indication, etc.). Still others demand that a generic applicant revise its application to encompass additional patents. All of the requests would add burdens on a generic applicant to comply. Thus, they are best classified as petitions with the potential to delay generics.

Another category of petitions has a less direct link to delaying generic approval. On occasion, pharmaceutical companies do not address specific generic applications or even the topic of generic approval in their citizen petition. Rather, the brand-name company requests that its drug receive additional exclusivities from the FDA or retain exclusivities that the company perceives to be under threat.[7] We have chosen to categorize these petitions as potentially related to generic delay because gaining exclusivity pushes back the window for generic entry. Interestingly, one petition filed by a pharmaceutical company even identifies the relationship between its exclusivity request and delay of generic competitors trying to enter the market.[8]

The final pool of citizen petitions with the potential to delay introduction of generic drugs consisted of 249 citizen petitions filed between 2000 and 2012. This number represents a striking portion of the citizen petitions filed at the FDA during that period. In fact, in our dataset, 22 percent of citizen petitions related in some way to drugs[9] and 14 percent of all citizen petitions filed on any topic at the FDA – including those related to food, medical devices, tobacco, and (everyone's favorite) dietary supplements – had the potential to delay the entry of generics.[10] Thus, the FDA is spending an inordinate amount of its time responding to citizen petitions aimed at delaying generic entry.

[7] For example, Petition No. FDA-2010-P-0188 asks the FDA to "confirm," among other related requests, that the "FDA will grant 180-day marketing exclusivity to Actavis' ANDA No. 77–302." *See* Citizen Petition from Axinn, Veltrop & Harkrider LLP, on behalf of Actavis Elizabeth LLC, to Div. of Dockets Mgmt., U.S. Food & Drug Admin., No. FDA-2010-P-0188, at 2 (Apr. 6, 2010), www.regulations.gov/#!documentDetail;D=FDA-2010-P-0188-0001.

[8] *See* Petition for Stay of Action from Arnold & Porter LLP, on behalf of Medicis, to Div. of Dockets Mgmt., U.S. Food & Drug Admin., No. FDA-2007-P-0295, at 1 (Apr. 20, 2007) (stating that "the requested stay would … prevent the approval of any ANDA or Section 505(b)(2) application referencing the Ziana™ NDA during the 3-year [*sic*] of market exclusivity that would be earned by the Ziana™ application if [the petitioner's other] citizen petition is granted") www.regulations.gov/#!documentDetail;D=FDA-2007-P-0295-0003.

[9] That is, 249 of 1,158 citizen petitions filed were related in any way to pharmaceuticals; 65 percent of all petitions (1,158 of 1,790) were related to pharmaceuticals.

[10] That is, 249 of 1,790 citizen petitions filed on any topic at the FDA.