

0-6 months. From this perspective, one can see that for a remarkable percentage of citizen petitions filed after 2007, approval for the relevant generic is occurring right around the time when the FDA must respond to the citizen petition. Specifically, from the middle of 2007 to 2012, we see a plurality of citizen petitions filed within six months of final generic approval.

This has two implications: first, many drug companies are filing citizen petitions as a last-ditch effort just months before generic approval; and, second, many of these citizen petitions may be the *last barrier* in the way of final generic approval. Anecdotally, this has certainly been the case for some petitions, as we saw in [Chapter 3](#).

Put another way, when so many generic applications are approved within six months – the equivalent of 180 days – of when a citizen petition is filed, and the FDA had 180 days to respond to a citizen petition, the relationship does not seem to be mere coincidence. This may also explain why the trend toward late citizen petitions is not as pronounced in the period before the 2007 Amendments: citizen petitions may have still been filed during the late stages of the FDA's consideration of generic applications, but since the FDA was not held to a specific deadline for responding to citizen petitions, lengthy petition reviews could have pushed back the horizon for final generic approval by more than six months. Delving deeper into this striking correlation between the FDA's deadline of 180 days and the plurality of citizen petitions filed within 180 days of generic approval would be an interesting avenue for future research.

#### 4 *Did the 2007 Amendments Do the Job?*

As described earlier, the 2007 Amendments require the FDA to respond to citizen petitions concerning generic applications within 180 days (shortened to 150 days in 2012); require those filing petitions to certify that the petition was not intentionally delayed and provide the date when the filer became aware of the concern; and give the FDA the power to deny petitions summarily in certain circumstances. Our study suggests that the 2007 Amendments have failed to stem the tide of citizen petitions intended to delay generic entry.

Imposing a deadline of 180 days for the FDA to respond may have reduced the length of the delay, but has by no means deterred the behavior. As detailed above, many competitor petitions continue to be filed late in the game, as a final attempt to delay competition just a little longer, even though they are unlikely to be successful. The same is likely true of the 2012 Amendments shortening the FDA's deadline to 150 days. The time is slightly shorter, but the incentives remain the same.<sup>32</sup>

<sup>32</sup> We cannot draw conclusions about the effects of the 2012 Amendments because our citizen petition data set only goes up to 2012. As discussed in Section A.2. above, we limited our data set to citizen