certainty the quarter in which an application was filed for nearly three-quarters of the generic applications in our pool.

In particular, the way docket numbers are assigned to generic applications makes it possible to estimate filing dates for those generic applications that do not have publicly available approval letters containing the filing date. To do this, however, we needed to look at the full set of generic applications approved by the FDA between the beginning of 2006 and the end of 2015, which consists of 4,222 applications.[12] 2006 was the starting point because we determined that very few drugs approved before this year were implicated in our set of citizen petitions filed between 2000 and 2012. 2015 was the ending point because it was the latest year for which generic approval data was available at the time we began collecting relevant information.[13]

Of the 4,222 generic applications approved between 2006 and 2015, 980 had exact filing dates available in approval letters, representing 23 percent. A further 2,108 filing dates were estimated using the process described above. In all, the quarter-year in which the generic application was filed was found or estimated for 3,088 generic applications, a success rate of 73 percent.

ii Matching Citizen Petitions to Relevant Applications

Having constructed the data set of filing and approval dates for generic applications, we then matched the data set of approximately 249 citizen petitions with the generic applications implicated by those petitions. In other words, what generic application would be most directly impacted, and potentially delayed, by the filing of that particular citizen petition?

Occasionally, the "offending" generic application would be explicitly named in the citizen petition.[14] In most cases, however, the target of the citizen petition's complaint was not so clear, perhaps because drug companies want to spread a wide net over all potential generic applications related to their existing drug. Similar to many citizen petitions, for example, Petition FDA-2009-P-0364 states, "Graceway respectfully requests that FDA refuse to approve any ANDA for a generic imiquimod cream

[12] We also matched the generic applications to the brand-name drug that was listed as the reference drug using the FDA's Orange Book data.

[13] In rare exceptions, we discovered a citizen petition in our data set related to a generic application that was approved prior to 2006. We were able to use the same techniques described in this section to fill in filing dates for the relevant generic application. Similarly, the FDA database of generic applications does not include approved 505(b)(2) applications. Thus, those applications were added as well, when necessary, for the 249 citizen petitions.

[14] For example, Petition FDA-2012-P-0184 specifically asks that the FDA "refuse to accept Cypress ANDA No. 20–2820 for filing (or find ANDA No. 20–2820 not approvable if already accepted for filing)." *See* Citizen Petition from Foley Hoag LLP, on behalf of Fresenius Medical Care North Am., to Div. of Dockets Mgmt., U.S. Food & Drug Admin., No. FDA-2012-P-0184, at 2 (Feb. 21, 2012), www.regulations.gov/#!documentDetail;D=FDA-2012-P-0184-0001.