product that seeks to rely on FDA's prior approval of Aldara, unless the application contains data from [bioequivalence studies, among others]."[15]

When a specific generic application was not identified, we turned to our generic application data set to find the first generic application filed that referenced the petitioner's drug.[16] The first filer is significant for a number of reasons – it opens the floodgates to generic competition, generating an initial drop in price and market share, as well as more substantial reductions as other generics enter later on. Thus, the first generic application is the most lucrative milestone for a brand-name company to delay or block.

Although we generally looked for the first-filed generic application as the appropriate reference point for a citizen petition, in a few instances the first filer could not have been the subject of the citizen petition, such as when the first filer was approved before the citizen petition was even filed. In those cases, appropriate steps were taken to identify the most relevant generic application.

At the conclusion of this process, 164 citizen petitions of the 249 originally identified were linked to a generic application that had data available – either a filing date, an approval date, or both.[17] This is a success rate of nearly two-thirds, or 65.9 percent, among the citizen petitions identified as having the potential to delay generic entry. Of those 164 petitions, 152 (or 61 percent of the total 249) were linked to generic applications with both the filing date and approval date.[18] In sum, out of the 249 citizen petitions with the potential to delay generic entry, we were able to establish at least partial timelines for the generic applications with which they were most likely associated for nearly two-thirds, and full timelines for 61 percent.

iii Establishing Key Metrics

Using our final data set of 164 citizen petitions paired with relevant generic applications with timing information, we were able to create a set of helpful metrics. The metrics we established included the following:

[15] *See* Citizen Petition from Graceway Pharm. LLC to Div. of Dockets Mgmt., U.S. Food & Drug Admin., No. FDA-2009-P-0364, at 2 (Jul. 30, 2009), www.regulations.gov/#!document Detail;D=FDA-2009-P-0364-0001.

[16] If multiple ANDAs were explicitly named in a petition, we identified the first-filed petition of those mentioned.

[17] In rare circumstances, a filing date was available but not an approval date. This occurred when a drug had only been tentatively approved but was still posted on the FDA's website with an attached letter noting the filing date.

[18] There were a total of 157 delay-related citizen petitions with filing information (including those with only a filing date and those with both a filing and approval date) and 159 delay-related citizen petitions with approval information (including those with only an approval date and those with both a filing and approval date).