4 Timing of the Citizen Petitions Relative to Generic Applications

For each of the 249 citizen petitions, we attempted to glean information about the timing relationship between the petition and the generic application most implicated by the petition. Namely, we wanted to know how much time had passed between when the relevant generic application was filed and when the citizen petition was filed. We also wanted to track how much time had passed between when the citizen petition was filed and when the generic application was approved.

Calculating these statistics required information on when generic applications were filed and approved. Although one would expect such information to be readily available in the FDA's public information, that is not the case.

i Filing Dates for Generic Applications

The FDA's searchable database contains readily available information regarding approval dates for most generic drugs, to the specificity of month and day. Filing dates, however, are not so transparent.[11] Assembling information on when a generic application was filed required a combination of sleuthing through the various letters in the generic drug's public file and estimating based on information known from other drug applications. The process allowed us to determine with reasonable

[11] Approval dates are, for the most part, readily available through the FDA's searchable database of approved drugs, known as Drugs@FDA. For example, anyone can search Drugs@FDA for information on ANDA No. 90153 (a generic version of Ambien CR), and the page clearly denotes an approval date of March 25, 2013. But *filing* dates are not so transparent. The FDA does not have a standard data field in Drugs@FDA for ANDA filing date – clicking the "Approval Date(s) and History, Letters, Labels, Reviews" link on the page for ANDA No. 90153 results in no history, letters, or documents whatsoever other than a table displaying the approval date for the drug. This was the case for the majority of generic applications we explored in the Drugs@FDA database. The only way we were able to obtain filing dates was through rarely posted approval documents on a drug's "Approval Date(s) and History, Letters, Labels, Reviews" page. For example, the Approval History table for ANDA No. 202958 (a generic version of Keppra XR, an antiepileptic) stores PDFs of the final approval letter and approved label for the generic. In the first line of the approval letter from the FDA to generic manufacturer Apotex, it references ANDA letter dated March 31, 2011, indicating the generic filing date. *See* Letter from William P. Rickman, Office of Generic Drugs, U.S. Food & Drug Admin., to Kiran Krishnan, Vice Pres., Reg. Aff., Apotex Corp., Re: ANDA 202958 (Feb. 25, 2015), www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/202958Orig1s000ltr.pdf. This – a brief mention in a PDF-only approval letter – appears to be the only way that filing dates have been made available to the public. We note that even that date may be slightly off. *See, e.g.*, 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), http://www.regulations.gov/#!documentDetail;D=FDA-2012-P-0184-0001 (date stamp one day later than the date of the letter). Other sources agree that this is the only location for filing dates. In late March of 2016, however, FDA commentators began to notice that the FDA had started to remove *all* filing dates from approval letters, eliminating the only public source of approval dates. (This also means that our study range cannot be extended past 2015.) *See* Bob Pollock, *Do You Notice Something Missing? What the Heck!* Lachman Consultants.com (Mar. 31, 2016), www.lachmanconsultants.com/2016/03/do-you-notice-something-missing-what-the-heck/.