documents that may be listed separately but correspond to a single citizen petition. The 19,520 documents are linked to a total of 1,790 citizen petitions filed between 2000 and 2012 and archived online.

3 *Identifying Citizen Petitions That Could Delay Generic Competition*

With the full data set of citizen petitions in hand, we turned to identifying citizen petitions with the power to delay pending or forthcoming generic applications. This process involved two steps for removing nonrelevant petitions: 1) removing petitions whose titles or categories indicated that they were unrelated to delay of generic competition, and 2) removing petitions by viewing the content of the petition and related documents in full.

After removing citizen petitions not relevant to our study, the remaining citizen petitions were those with the potential to delay a pending or forthcoming generic competitor. The decision to include a citizen petition in the data set was based solely on the topic of the petition, and no attempt was made to judge the merits of the issues raised in the petitions.

Many of the citizen petitions in the final pool specifically ask the FDA to stay or delay approval of a generic application. These frequently raise concerns about safety or incomplete bioequivalence or clinical testing, with bioequivalence testing a particularly prevalent topic. Many of these petitions ask the FDA to stay the approval of a generic drug until the generic applicant presents evidence that the FDA already requires. This type of petition essentially forces the FDA to make a redundant ruling that a certain type of testing is required, when in fact, that testing is already required.

These redundant petitions lead to a number of FDA rulings that grant petitions while not actually imposing any new requirements on the generic applicant. The result may be a petition that is granted in part and denied in part, with the granted portion no more than a formality that lacks practical significance.[5]

Consider the FDA's response to a citizen petition that requested a stay of generic versions of Argatroban, a drug to prevent blood clotting. In its response, the FDA acknowledges that the actions granted in the petition are merely those already required under FDA policy, stating that "[t]o the extent it is consistent with our current policies, we grant your request."[6] In plain terms: we already require this, so we grudgingly agree.

[5] *See* Carrier & Wander, *Citizen Petitions*, *supra* note 2, at 261, 266; *see also ibid.* at 261 (noting that the FDA's director of the Office of Generic Drugs has made a similar observation, saying, "when petitions are granted, in whole or in part, it is often because the FDA already has the proposed scientific or legal standard in place or is already planning to take the action that the petition requests").

[6] Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., to Richard D. Kelly, Oblon Spivak, on behalf of Mitsubishi Tanabe Pharma Corp., Re: No. FDA-2009-P-0115, at 8–9 (Aug. 19, 2009), www.regulations.gov/#!documentDetail;D=FDA-2009-P-0115-0006.