A Topic-Based Analysis Of FDA Responses To FOIA Requests

By **Bradley Thompson** (September 21, 2023)

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In today's environment filled with misinformation, it is especially important for businesses to critically understand regulatory processes such as those of the U.S. Food and Drug Administration. For that reason, the Freedom of Information Act process should be fair and efficient.

Previously, I **discussed** my journey to analyze FOIA data on all the requests made over a 10-year period. As I continue to analyze the 118,000 requests in this article, I focus on my method using topic modeling, an analysis of response time outcomes by topic including which topics succeed and which do not.

Topic Analysis

Using topic modeling, a natural language processing algorithm that is a form of machine learning, we can discern the major topics of FOIA requests.

It turns out an optimal number of topics to use for sorting is 20. While it is important to understand the algorithm is not reading these as a human would, it is also not a bad thing. The algorithm is looking for requests using similar words.

This is a blend of art and science. The actual data set is composed of about 120,000 different requests submitted by tens of thousands of people, each with different motivations along a sort of continuum. The topics are quite human and messy. Some are very similar while others are only slightly similar. There is no reason to believe that the categories would be obvious and completely distinct from one another.

Of the 20 topics, shown **here**, the ones that are easier to understand and interpret into somewhat defined categories include the following:

- Complaint Investigation and Adverse Events;
- Drug Inspections;
- Form 483 or Establishment Inspection Report Drug;
- Nondisclosure Agreement and Adverse Event Report;
- Warning Letters;
- Specific Correspondence;
- Follow-On FOIA;
- Section 510(K);
- Form 483s for Indian Facilities;
- Meeting Minutes; and
- Medical Device Inspection.

With those topics identified, I wanted to see which ones were more frequent than others, by building **a graph** that showcases the number of FOIA requests submitted per topic over a 10-year period.

The so-called follow-on FOIA request piggybacks on a prior FOIA request and asks for the

same information that was provided to the previous requester.

It is a strategy for speeding up the process because it alerts the FDA they have already done what is being asked.

Getting down to specific program areas, 510(k)s in the medical device arena are immensely popular to obtain because you can learn so much about a competitor but also about the regulatory pathway for your product.

Thus, it makes sense for it to be toward the top, meaning a higher number of requests.

The Indian 483s in fourth position surprised me. I had no idea it was so popular, so I looked at a sampling of them in the data.

Turns out there are over 2,200 FOIA requests related to Form 483s for Indian facilities from a variety of media, private equity, information merchants, pharmaceutical companies and a whole lot of others. Who knew?

But my chart actually suggests there are over 8,000 such requests, which is not true and raises a key point.

The word India is fourth on the list of relevant words to topic 13, so perhaps it is not fair to characterize the entire topic as related to India. It seems more about inspectional 483s.

In that sense, the topic seems to overlap with topic number four which also is focused on 483s, but in equal measure focused on establishment inspection reports.

The topic modeling algorithm is finding a subtle distinction between those two, which acts as an important reminder that these are not neat, clean, separate and distinct topics.

Given that data on frequency, I wanted to create **a graph** of FDA response times broken down by these same topics.

A quick review reveals significant differences in response time between, for example, requesting a copy of a submitted 510(k) that must be reviewed for confidential information and redacted, and for a follow-on FOIA where the previous response simply needs to be identified and shared with the new requester.

The average response time is around 45 days.

The fact that the very most requested information is Form 483s with ancillary information makes sense because that cuts across all product areas at the FDA — food, drugs, medical devices, etc.

To note, the graph reveals this topic to have the most requests over the past 10 years — around 15,000 — where some of the least requested topics include drug facility and medical device inspections.

Further, many people are interested in trying to understand the issues that the FDA is raising in Form 483s.

The fact that the FDA now has an enforcement dashboard[1] that allows for the release of this information may mean it is not quite such a popular FOIA request over the next 10

years.

Now, let's focus on the average response times broken down by category.

It seems logical the top would include the 510(k) requests because those are frequently lengthy documents that must be reviewed through a very manual process at the FDA, and with the help of the applicant, to remove any confidential commercial information before they are released.

In fact, on the FDA's FOIA website, they warn that 510(K) requests take a long time.

The FDA states, "Please note that requests for 510K, PMA, and De novo records are complex requests and take approximately 18-24 months to process."[2]

The FDA's statement, however, is pessimistic because the average time for these requests according to the data is about nine months.

It appears like the FDA wants to discourage these requests or has gotten substantially slower over the last 10 years in responding to these requests.

One that caught my eye was the request for specific correspondence.

I believe a request can take so long because the request is often not for a specific letter, but rather for all correspondence between XYZ company and the FDA. Thus, it would take the agency a while just to collect all that correspondence, and then redact it.

It makes sense the follow-on FOIA requests would be comparatively quick to get responses because that is the whole purpose of them. People are requesting information that has already been supplied, so it does not need to be collected and redacted.

Success Analyzed by Topic

Given the topics previously identified, I wanted to understand which topics are likely to succeed in getting information from the FDA.

That said, **this graph** shows the number of requests per topic, where each topic's "number of requests" bar is broken out into various colors, to show you the different percentages of request outcomes per topic. For example, a few of the outcome options include closed, duplicate request, open, no records, reroute and withdrawn closed without charge.

Thus, for example, for the FOIA topic of a "483/Adverse Event Report," over all the requests for the last 10 years, requesters are 69% likely to get a "closed" response, which means that the FDA sends responsive documents.

In sum, success rates vary considerably by topic, with follow-on requests not surprisingly being among the most successful and topics like medical device inspections being among the least.

Who's Asking What

I was then interested in exploring at a deeper level which particular organizations were requesting these particular topics.

The best way to present the high-level information here is to take the top 20 requesters and use **a heat map** to explore the relationship between the requesters and the topics.

The deeper the color, the more the requester is asking about those topics at the intersection of the requester and topic lines.

So, for example, it is apparent that FDAZILLA submitted a whole lot of topic number 10 requests.[3] On the other hand, the white spots indicate areas where particular firms did not ask any significant number of requests.

Who Is Successful

The final question I wanted to explore was success rates for different requesters. **This chart** shows the number of requests a given requester made, while the colors indicate the outcome of the request.

FOI Services Inc. submitted a lot of requests, but their success rate was proportionately not as good as FDA News, for example.

The chances of success in a FOIA request apparently depend heavily on the topic generally. It should not be any surprise that a follow-on request is highly successful, 80%. That is because all the hard-work and debate went into the original request.

Of course, it is possible for people to file a follow-on request before the earlier request has even been resolved, so those follow-on requests might account for at least part of the 20% that did not succeed.

Getting a particularly low score is meeting minutes, which only succeeds about 42% of the time. That is not surprising, because typically someone would ask for meeting minutes for probably a sensitive topic that might reflect either ongoing policymaking or enforcement efforts. Those would be rejected as exempt from disclosure under FOIA.

Warning letter requests do not fare much better at 54%. Obviously, people are not asking for the warning letter itself as that is publicly released already. They are apparently asking for enforcement related documents that led up to the warning letter. Many of those, if requested soon after the warning letter, would be exempt from release as part of a not yet completed enforcement action.

Requests related to 510(k)s have a pretty high success rate at 73%, but as my previous article indicated, you need to be really patient when you request that. It can take a couple of years.

The lowest success rate relates to what looks like a somewhat specific request — topic 19 — which somehow involves pet food and emails about it, as well as the Association of American Feed Control Officials.

Regarding that, I would guess that there was some controversy about a pet food regulatory model developed by AAFCO that requesters wanted information about. Those FOIA requests were only successful 37% of the time.

I think it is interesting to then see who is asking about these various topics, and what their individual company success rates are. As you can see from the heat map, Merck & Co. Inc. likes to submit follow-on FOIA requests, and when you look at the chart about company

success rates, Merck is very successful in it. That makes sense. As already noted, follow-on FOIA requests are among the most successful.

FOI Services, on the other hand, likes to ask for a lot of 510(k)s. But they also asked for just about everything else. Overall, their success rate is much more mixed.

FDA News, which does more investigative reporting, was very interested in the Indian 483s as well as 483s more generally. Interestingly, they have a very high success rate, even though those individual topics do not have as high a success rate generally.

Conclusions

Your success in getting information from the FDA is, not surprisingly, tied to the topic about which you are requesting. But it also seems to be tied to who you are. Or maybe it is less about who you are, and more about how competent you are.

Not all requests are equally well written. Nor are they equally well timed. People who ask for information prematurely before the agency is done with its confidential work are more likely to be unsuccessful in getting it.

There are a lot of factors that go into whether a request is successful even if it is on a very similar topic.

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[1] https://datadashboard.fda.gov/ora/cd/inspections.htm.

[2] https://www.fda.gov/regulatory-information/freedom-information/how-make-foia-request.

[3] https://www.healthlawadvisor.com/2023/05/02/unpacking-averages-success-rates-for-fda-foias-by-topic-and-requester/.