EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, -against- FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 4:21-cv-01058-P

DECLARATION OF SARAH B. KOTLER

I, Sarah B. Kotler, declare as follows:

1. I am the Director of the Division of Freedom of Information (DFOI), Office of the Executive Secretariat, Office of the Commissioner, Food and Drug Administration (FDA), United States Department of Health and Human Services (HHS), in Rockville, Maryland.

2. I have held the position of Director of DFOI since January 2015. Prior to becoming Director, I served as Acting Director of DFOI from November through December 2014, after the former Director of DFOI retired. I previously served as DFOI's Deputy Director and Denial & Appeals Officer from September 2013 through October 2014; and as Denials & Appeals Officer from March 2007 through August 2013.

3. As both Deputy Director and Director, I have had supervisory authority over DFOI, which serves as FDA's official point of receipt for all requests for records under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. *See* 21 C.F.R. § 20.40. In addition, DFOI is responsible for FDA's FOIA reporting to HHS and the U.S. Department of Justice, consulting with other federal agencies regarding FOIA requests, agency-wide FOIA training, and expedited

processing, among other functions. DFOI processes about 25% of all FOIA requests received by FDA; the other 75% are processed by the FOIA reviewers within FDA's other components.

4. As part of my duties, I have been coordinating FDA's processing of FOIA requests that relate to the novel coronavirus known as SARS-CoV-2, also known by the disease it causes, COVID-19. Due to the nature of my official duties, I am familiar with the procedures followed by FDA in responding to requests for information from its files pursuant to provisions of the FOIA, 5 U.S.C. § 552, among others. I am aware of the workload obligations of the various offices that process FOIA requests across the agency.

5. The statements contained in this declaration are based upon my personal knowledge, upon information provided to be in my official capacity, and upon conclusions I reached based on that knowledge or information.

6. The purpose of this declaration is to provide an overview of FDA's procedure for handling FOIA requests and its capabilities in processing Plaintiff's FOIA request in particular. This declaration also documents the agency's basis for denying Plaintiff's request for expedited processing.

7. As explained below, Plaintiff's Request did not satisfy the standard for expedited processing because it did not establish an urgent need to inform the public about federal government activities. Further, Plaintiff's suggestion that FDA should be able to reallocate resources to respond to Plaintiff's FOIA request is not feasible and could violate FDA's obligations with respect to other FOIA requesters. Since the beginning of the COVID-19 pandemic, FDA has experienced a sudden surge of incoming FOIA requests, an increase in the complexity of those requests, and an uptick in the amount of FOIA litigation it faces. These factors, when combined with the Agency's existing FOIA and non-FOIA workload, prevent

other FDA components from being available to assist the Center for Biologics Evaluation and Research ("CBER") to process Plaintiff's Request without diverting significant resources away from the processing of other FOIA requests that are also in litigation, requests that are ahead of Plaintiff's, as well as other non-FOIA record requests. Such diversion would adversely impact the Agency's ability to meet stipulated document processing deadlines and prejudice other pending requests.

FDA'S GENERAL PROCEDURE FOR INCOMING FOIA REQUESTS

8. Under FDA's regulations, DFOI is the office responsible for FDA's compliance with FOIA. *See* 21 C.F.R. §§ 20.30, 20.40. When DFOI receives an electronic FOIA request, it generates a control number that begins with four digits reflecting the calendar year in which the request was received, followed by the number of FOIA requests received by DFOI to date in that particular calendar year. For example, Plaintiff's request has the control number "2021-5683" because it is the 5,683rd FOIA request received by FDA in calendar year 2021.

9. FDA provides expedited processing of a request for records when the requester demonstrates a compelling need and in other cases determined by the agency. *See* 5 U.S.C. § 552(a)(6)(E). A compelling need exists when: (1) A failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or (2) With respect to a request made by a person primarily engaged in disseminating information, there is a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity. *Id*. DFOI reviews requests for expedited processing and sends a letter to the requester documenting FDA's determination as to whether expedited processing has been granted or denied. In accordance with 21 C.F.R. § 20.44, requests that have

been granted expedited processing are processed as soon as practicable, on a first-in, first-out basis based on the date of receipt.

10. Because of FDA's size and the large number of records generated during the course of agency business, and the different components within FDA, the agency's FOIA program is decentralized. After a FOIA request is received and logged by DFOI, the request is assigned to the FDA components reasonably likely to possess responsive records, which then process the request. FOIA reviewers within each assigned component process potentially responsive records and determine whether they should be released in full, redacted in part, or withheld in their entirety under any applicable FOIA exemption or other statutory or regulatory provision.

FDA'S PUBLICATION OF INFORMATION RELATED TO COMIRNATY VACCINE

11. In an effort to inform the public about its work related to COVID-19, FDA has made an abundance of information available on its website – both about the Comirnaty vaccine specifically and the agency's COVID-19 response generally. The homepage of FDA's website prominently features a link to information about the "FDA COVID-19 Response." FDA, https://www.fda.gov/. Clicking on that link takes the user to a page with numerous links to additional information about FDA's response. The linked webpages provide information about COVID-19 vaccines, emergency use authorizations, personal protective equipment, FDA guidance documents, Frequently Asked Questions, and resources for health professionals, among many other things. FDA, Coronavirus Disease 2019 (COVID-19), https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19.

12. From that page, the user can access the "Comirnaty and Pfizer-BioNTech COVID-19 Vaccine" page. FDA, Comirnaty and Pfizer-BioNTech COVID-19 Vaccine,

https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine#comirnaty (printout attached as Exhibit A to this declaration). That page contains links to a host of important information about the Comirnaty vaccine, including Frequently Asked Questions for Comirnaty, information sheets for healthcare providers, regulatory information, media materials and webcasts, advisory committee information, and even links to video recordings of virtual meetings of FDA's advisory committee (the Vaccines and Related Biological Products Advisory Committee). *Id.* The webpage even includes translations of certain information in multiple languages, including Spanish, Chinese, Korean, Russian, among many others. *Id.*

13. Clicking on the "Comirnaty Information" link on that page brings the user to yet another page with more information specific to the Comirnaty vaccine. FDA, Comirnaty, https://www.fda.gov/vaccines-blood-biologics/comirnaty. This page contains the "Action Package" for Comirnaty, required by the Food and Drug Administration Amendments Act of 2007 to be posted within 30 days of approval. The agency expects the Action Package to be of interest and most useful to the public in understanding its approval decision. It provides access to the package insert, the Summary Basis for Regulatory Action, the Approval Letter, FDA decision memoranda, and approval history. Many of these records were posted shortly after the Comirnaty biological license application ("BLA") was approved on August 23, 2021. For example, FDA posted its "Summary Basis for Regulatory Action" the day after the Comirnaty BLA was approved; it posted the Action Package, including FDA discipline review memos such as clinical, statistical and toxicology reviews, approval letter, and package insert, within 25 days of approval. FDA's Comirnaty page currently contains links to approximately 700 pages of Action Package records related to the Comirnaty vaccine licensure. *Id.* These records often contain summaries of

the information and data submitted by Pfizer and BioNTech that FDA reviewed and assessed, as well as FDA's assessment, that support FDA's decision to license the Comirnaty vaccine. As just one example of the types of information available, there is a 107-page August 23, 2021, "BLA Clinical Review Memorandum." That memorandum includes sections entitled, "Clinical and Regulatory Background," "Submission Quality and Good Clinical Practices," Significant Efficacy/Safety Issues Related to Other Review Disciplines," Discussion of Individual Studies/Clinical Trials," and the FDA reviewers' conclusions and recommendations based on the data reviewed. *See id.* (under link to "Approval History, Letters, Reviews, and Related Documents – COMIRNATY").

14. FDA continues to regularly update these websites to provide the most current and relevant information about COVID-19 to the public as soon as possible.

FDA'S PROCESSING OF PLAINTIFF'S REQUEST

15. On August 27, 2021, Plaintiff submitted to FDA a request ("Plaintiff's Request") seeking, "[a]ll data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System." Plaintiff's Complaint, ECF No. 1-1, Ex. A.1 at 1. FDA assigned Plaintiff's Request the control number 2021-5683. Plaintiff's Request is extremely broad, calling for the agency to review the entire BLA for the Pfizer-BioNTech Comirnaty COVID-19 vaccine to determine which information is available for release to the public under 21 C.F.R. § 601.51(e).

16. I assigned Plaintiff's Request to CBER for processing because it sought information – a BLA – in CBER's custody. CBER's processing of Plaintiff's Request is described in more detail in the December 6, 2021, Declaration of Suzanne Burk ("Burk Decl."), ECF No. 23 at Ex. A. As described in that declaration, CBER expended great efforts to negotiate the scope of

Plaintiff's request—and in particular, to supply Plaintiff with information it could use to narrow its Request to a more manageable universe of documents, which the FDA could, correspondingly, process more quickly—as well as a production schedule for Plaintiff's Request. However, to date, the parties have not been able to agree to either any modification of the scope of Plaintiff's request, or to a production schedule. *See* Burk Decl. ¶¶ 26-27.

REQUEST FOR EXPEDITED PROCESSING

17. Plaintiff's Request included a request for expedited processing. I carefully reviewed that request for expedited processing, and I determined that Plaintiff did not demonstrate a compelling need under 5 U.S.C. § 552(a)(6)(E), in substantial part because of the large amounts of information that have already been made available to the public about the Comirnaty vaccine and related FDA activities. A compelling need exists when: (1) A failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or (2) With respect to a request made by a person primarily engaged in disseminating information, there is a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity. *Id*. Department of Justice guidance advises agencies to "carefully" assess the merits of expedited processing requests "[b]ecause the granting of a request for expedition necessarily works to the direct disadvantage of other FOIA requesters." U.S. Department of Justice, FOIA Update: OIP Guidance: When to Expedite FOIA Requests, https://www.justice.gov/oip/blog/foia-update-oip-guidance-when-expedite-foia-requests.

18. Plaintiff's Request did not contain any basis to conclude that a failure to obtain records on an expedited basis would pose a threat to any individual. As a result, I concluded that Plaintiff had not satisfied the first criterion for expedited processing.

19. Plaintiff's Request did assert that Plaintiff was an organization primarily engaged in disseminating information and explained why it believed it was urgent to inform the public about government activities related to the Comirnaty vaccine. Plaintiff first explained that it believed that there was an "ongoing, public national debate" about FDA's decision to license the Comirnaty vaccine, quoting numerous individuals, including a number of Plaintiff's members, with varying opinions about the vaccine. Second, Plaintiff noted that many organizations had mandated COVID-19 vaccines for their members or employees.

20. After considering Plaintiff's explanation, I determined that Plaintiff had not established that it had demonstrated urgency to inform the public concerning actual or alleged Federal Government activity, largely because there is a significant amount of information already available to Plaintiff and the public concerning FDA's activities surrounding the Comirnaty vaccine. As discussed above (*see*, *supra*, ¶¶ 11-14), FDA is posting a significant amount of information related to the Comirnaty vaccine on its website on an ongoing basis. The documents posted by the agency currently contain, among other things, FDA review memoranda, which include summaries of safety and effectiveness data, as well as FDA reviewers' analyses of them. FDA's sister agency, the Centers for Disease Control and Prevention ("CDC") also maintains a website with additional information about Comirnaty ingredients, summaries of safety data, and clinical trial evidence about efficacy. CDC, Pfizer-BioNTech COVID-19 Vaccine (also known as COMIRNATY) Overview and Safety, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html. CDC also provides the public with access to its WONDER database, which contains adverse event report data collected through the U.S. Vaccine Adverse Event Reporting System. CDC, How to Access VAERS Data through VAERS WONDER System, https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/

vaers/access-VAERS-data.html. As a result, the public has access to a large amount of information about the vaccine and government actions related to the vaccine's review and approval.

21. The fact that people may have differing opinions about a certain FDA-regulated product does not create "urgency" within the meaning of the expedited processing standard for the agency to produce an entire BLA – especially in light of the amount of information published on FDA's website. Nor does the fact that certain individuals may be administered a certain product. FDA approves medical products regularly in the course of agency business. It is not unheard of for those approvals to be the subject of controversy, and there are almost always people who are administered the products shortly after approval. Such a situation cannot be deemed to create an urgent need for the agency to expedite its review and processing of the hundreds of thousands of pages of records, especially when the agency routinely publishes summaries of safety and efficacy information on its website (as it did here). If Plaintiff's view became the standard, a great number of FDA's FOIA requests would qualify for expedited processing, and requesters with non-expedited requests would have their wait times extended – possibly significantly. Thus, Plaintiff's claim that its request would fulfill an urgent demand is not supported, and I denied its request for expedited processing.

ALLOCATION OF AGENCY RESOURCES

22. I understand that Plaintiff has suggested that FDA should reallocate resources from other agency functions to help process Plaintiff's Request. This suggestion is not feasible, or even beneficial, for a number of reasons. First, performing disclosure reviews is a specialized skill that requires training and expertise that the vast majority of FDA staff does not have. It is not reasonable to expect that a microbiologist who performs laboratory assays, a pharmacist who reviews drug applications, a badging office employee who issues credentials, or a mail room clerk

who organizes mail can simply begin performing disclosure review without significant training. Moreover, it would be contrary to FDA's public health mission to pull staff off reviewing cancer treatment applications or building counterfeit medication investigations to have them conduct work for which they are untrained and unqualified. Second, as Director of DFOI, I do not have authority to order FDA staff from other program offices – many of whom are actively involved in the agency's extensive efforts to respond to the COVID-19 pandemic – to support the agency's disclosure functions. Further, even if the agency did suddenly allocate significant new monetary resources to hire new disclosure staff, it would take substantial time to recruit and hire new staff, bring them on board, and provide them with the necessary training to become competent to perform disclosure reviews. FDA estimates that it takes approximately two years to fully train a new disclosure reviewer. In the meantime, experienced reviewers would be needed to supervise and review their work – thus decreasing the amount of time that experienced reviewers can spend reviewing records. As a result, it is not reasonable to expect that FDA will be able to respond to Plaintiff's Request more quickly by allocating non-disclosure resources to processing it. In fact, to do so would significantly impede FDA's public safety role.

23. And, as discussed in the following section, it is not feasible for the agency to reallocate its existing disclosure resources to work on Plaintiff's Request because the agency's disclosure staff is already over-extended by existing disclosure obligations.

PROCESSING WORKLOAD OF DISCLOSURE OFFICES OUTSIDE OF CBER

24. As an initial matter, the disclosure office of each FDA component has its own specialized responsibilities and expertise. Thus, although all disclosure staff will be familiar with general principles of FOIA, staff from different centers will be trained to review information regularly generated within that center. For example, CBER reviewers are familiar with the types

of information regularly contained in BLAs and are trained to identify information that may be exempt from disclosure in those types of files; CBER reviewers would not be familiar with the types of records commonly processed by other parts of the agency, such as premarket tobacco product applications or food additive petitions. The converse is also true; reviewers in FDA's Center for Food Safety and Applied Nutrition ("CFSAN") are familiar with records regularly generated within CFSAN, but would not have the same expertise as a CBER reviewer when looking at a BLA. Thus, even disclosure staff within the agency should not be considered interchangeable.

25. Further, on March 13, 2020, the President declared a national emergency due to the ongoing COVID-19 pandemic. Since the beginning of this emergency, FDA has been flooded with FOIA requests related to the pandemic.

26. Specifically, in the last fiscal year, FDA received approximately 8,529 FOIA requests, many of which are directly related to COVID-19. Of these, an extremely high 99 requests (1.16%) have been granted expedited processing. Historically, FDA has had fewer than five expedited requests at any one time, and often fewer than five. For example, in 2019, FDA granted expedited process for only 0.017% of requests received. In short, the number of FOIA requests meriting expedited processing has grown exponentially since the beginning of the COVID-19 pandemic.

27. Further complicating matters, many of the more recent FOIA requests are more complex and are expected to take longer to process than typical FOIA requests received prior to the beginning of the COVID-19 pandemic. Many requests for information related to COVID-19 require collaboration among federal agencies because they involve records (such as emails) that may have originated in other agencies. Department of Justice guidance advises federal agencies

to consult with the originating agency for disclosure determinations. U.S. Department of Justice, FOIA Update: OIP Guidance: Referral and Consultation Procedures, https://www.justice.gov/oip/blog/foia-update-oip-guidance-referral-and-consultation-procedures. As a result, FDA regularly collaborates with other federal agencies, such as CDC, the National Institutes of Health, and the Department of Health and Human Services, about records responsive to requests. These consultations add both time and complication to the process for responding to FOIA requests.

28. Coupled with the unprecedented number of FOIA requests that merit expedited processing and the increased complexity of requests, FDA recently experienced a significant increase in FOIA litigation. Between calendar years 2017 and 2019, the number of FOIA lawsuits filed against the Agency grew by approximately 70%; between calendar years 2018 and 2020, the number of FOIA lawsuits filed against FDA grew by approximately 200%. Although the number of lawsuits so far in 2021 has decreased from 2020 levels, FDA has been the subject of 11 lawsuits in 2021, which is an increase of 83% from 2018 level. Currently, FDA is involved in approximately 34 active FOIA litigations, with nine matters involving COVID-19 records.

29. At the review and redaction phase, certain FDA components have had to shift some of their FOIA reviewers from responding to FOIA requests in the normal course to almost exclusively processing FOIA requests in litigation. This diversion of staff resources to respond to ever increasing litigation and impending court deadlines means that fewer initial FOIA requests are being processed, and at a slower pace, which is causing even more litigation.

30. In addition to FOIA, FDA also has numerous other document processing obligations, including those arising from subpoenas; non-FOIA litigations; oversight requests from Congress; requests and domestic and foreign regulatory bodies; and other statutory disclosure

mandates. In some agency offices, the same staff that handles FOIA requests also handles these other disclosure projects as they rely on similar disclosure skills. As a result, it would not be feasible for FDA to shift resources from other disclosure offices to help CBER process Plaintiff's Request. In the following paragraphs, I discuss the current workload of various FDA components.[1]

Center for Drug Evaluation and Research ("CDER")

31. As of November 30, 2021, CDER is responsible for processing 855 pending FOIA requests. This is a significant increase in pending requests compared to past years, partly due to increased burden resulting from work related to COVID-19 FOIA requests and other disclosure obligations. CDER is responsible for processing at least 170 FOIA requests related to COVID-19. The following chart illustrates the increase in the length of CDER's FOIA queue as of November 30 of each calendar year.

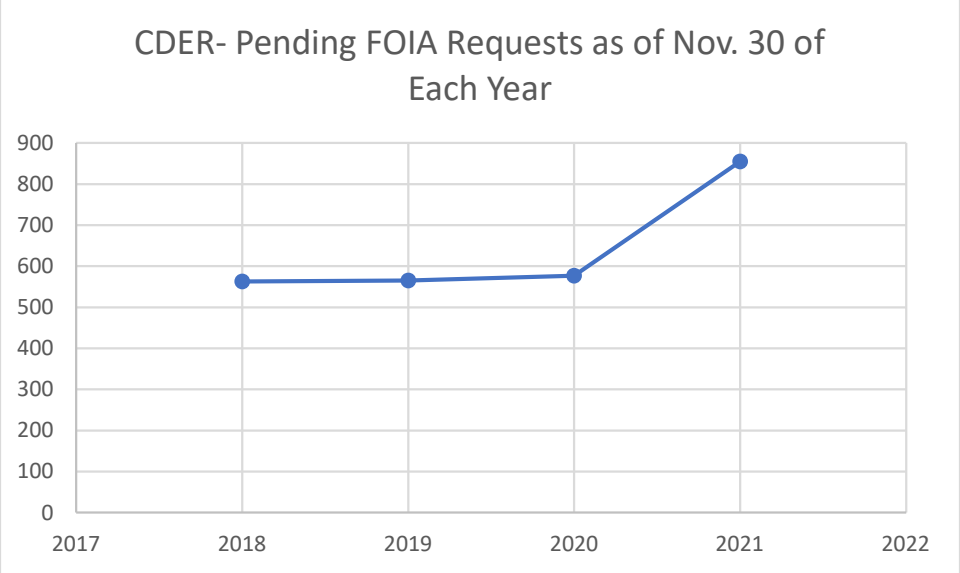

Figure 1: *Pending FOIA Requests in CDER as of November 30 of each year from 2018 to 2021.*

[1] I do not include a discussion of CBER's workload because that information was included in the December 6, 2021, Burk Declaration. ECF No. 23, Ex. A.

32. In addition to processing FOIA requests, CDER is also responsible for processing other document requests made by Congress; the U.S. Government Accountability Office; foreign, state, and local governments; and other federal agencies. Although these requests are not made under FOIA and are not processed in CDER's FOIA tracks, they are processed by CDER's FOIA reviewers because of the similar nature of the work to FOIA processing and the need for consistency in reviewing and redacting responses to information requests. Since 2019, these responses have required the attention of up to four employees. Because some of these employees were pulled from other tasks to work on these matters, there was a corresponding decrease in reviewers' time available to respond to FOIA requests. In recent years, CDER has produced tens of thousands of pages in response to requests from foreign regulatory authorities for documents regarding FDA inspections of foreign drug manufacturers, and in response to requests from the Department of Justice related to its investigations of pharmaceutical companies. CDER also has other statutory disclosure obligations under the Food and Drug Administration Amendments Act of 2007, which requires that New Molecular/Biological Entity (NM/BE) action packages be published on CDER's web page within 30 days of approval. In 2019, CDER reviewed and redacted 46 NM/BE action packages, and in 2020, CDER reviewed and redacted 20 NM/BE action packages, each of which typically contains thousands of pages.

Office of the Commissioner ("OC")

33. As of November 30, 2021, OC has 435 pending FOIA requests. At this time, OC has 1 full time employee working on FOIA requests. Since the fall of 2020, OC has brought in detailees for 90 to 120 day periods to assist the FOIA FTE. Despite my other duties, including management of my division, I have been assisting with FOIA review for COVID requests in OC, as well as keeping the non-COVID OC FOIA workload moving. OC is currently involved in 8

active litigation matters. As with CDER, this represents a significant increase in pending requests compared to past years. The following chart illustrates the increase in the length of OC's FOIA queue as of November 30 of each calendar year.

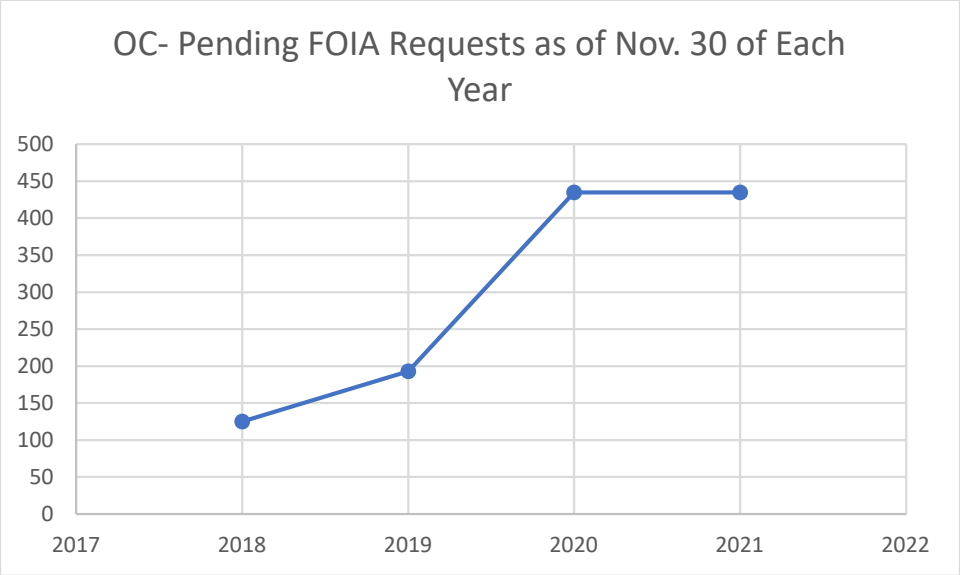

Figure 2: *Pending FOIA Requests in OC as of November 30 of each year from 2018 to 2021.*

Center for Devices and Radiological Health ("CDRH")

34. Currently, CDRH has 2,010 pending FOIA requests, approximately 124 of which are related to COVID-19. The following chart illustrates the length of CDRH's FOIA queue as of November 30 of each calendar year. Although CDRH's queue has not changed as dramatically as other FDA components, it remains the longest queue in the agency.

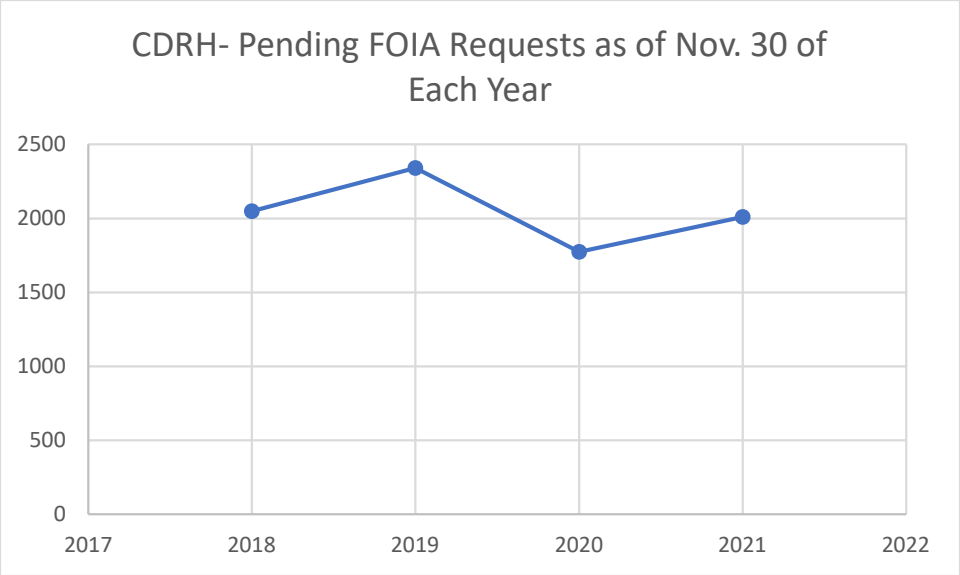

Figure 3: *Pending FOIA Requests in CDRH as of November 30 of each year from 2018 to 2021.*

35. Other than FOIA requests, CDRH's FOIA Office is also responsible for responding to subpoenas and non-FOIA record requests made by Congress; foreign, state, and local governments; and other federal agencies. Since 2015, these responses have required the attention of up to 22 employees. Because some of these employees were pulled from other tasks to work on these matters, there was a corresponding decrease in reviewers' time available to respond to FOIA requests. Within the past four years alone, CDRH produced tens of thousands of pages of documents in response to requests from other federal agencies related to their investigation of medical device companies. Furthermore, since 2018, CDRH has responded to numerous federal subpoenas, with quick turnarounds for productions that have required CDRH reviewers to stop processing FOIA requests to respond to these subpoenas. Specifically, two of the subpoenas have yielded over hundreds of thousands of pages each.

Other FDA Components

36. The components highlighted above are not outliers. Other FDA components have significant queues, some of which have grown recently as a result of increased workload related

to COVID-19. For example, the Office of Regulatory Affairs alone has devoted over 1,500 hours to responding to COVID-19 FOIA requests and has seen its number of pending requests increase from 28 in November 2018 to 91 in November 2021. Although largely unrelated to the COVID-19 pandemic, FDA's Center for Veterinary Medicine has seen its number of pending requests jump from 102 in November 2018 to 318 in November 2021, due to an increase of FOIA requests unrelated to COVID-19.

37. FDA's Center for Food Safety and Applied Nutrition and Center for Tobacco Products have not encountered the same influx of COVID-19 FOIA requests, so their FOIA queues have remained fairly steady in the 2018-2021 timeframe. But they continue to maintain queues in the 65-75 range, so their resources are fully consumed with their standard responsibilities, which also include non-FOIA disclosure projects, such as Privacy Act requests.

38. Based on all of the information above, none of FDA's other disclosure offices are able to assume the burden of taking on a significant role in the review of CBER records responsive to Plaintiff's Request without compromising their ability to keep up with their own disclosure review responsibilities, especially considering that these staff are not specifically trained to review the records at issue in this case.

EFFORTS TO REDUCE BACKLOGS

39. FDA's various FOIA offices have taken numerous steps to reduce backlogs and improve processing time. Specifically, FDA's FOIA offices are recruiting and hiring new employees where funding allows; proactively posting online frequently requested documents to reduce the need for new FOIA requests; cross-training employees in complex disclosure matters to assist with complex track requests; evaluating requests daily in order to shift them to experienced redactors as needed; and, where possible, proactively contacting FOIA requesters to

negotiate the scope of requests to in order to produce documents quickly. In particular, since August 2020, CDER has brought on six new employees to assist with FOIA processing. Similarly, CDRH completed a business process improvement review of its FOIA program in October 2019, which included identifying hiring needs; updating workflows, processes, and procedures; training reviewers; and additional tracking of FOIA requests. Between September and December 2019, CDRH acquired a multi-year contract that currently provides seven contractors to assist in reducing FOIA backlogs and hired additional full-time reviewers to process FOIA requests and other disclosure tasks. Unfortunately, this review was conducted before the onslaught of COVID-related FOIA requests were submitted, and therefore the process changes have not achieved results as quickly as expected.

CONCLUSION

40. In sum, FDA is committed to transparency in all aspects of its work, especially its response to the COVID-19 pandemic. The agency has taken proactive steps to provide an abundant amount of information to the public about the Comirnaty vaccine as soon as possible. That information is available on FDA's website, which is being updated regularly. FDA has also taken reasonable steps to respond to Plaintiff's Request, as discussed in greater detail in the Burk Declaration. But Plaintiff's Request does not satisfy the statutory standard for granting expedited processing. Further, given the limited number of FDA staff available to perform disclosure reviews and the heavy workload FDA's disclosure offices are facing, it would be unduly burdensome for FDA to reallocate resources from agency components other than CBER to process Plaintiff's Request. If required to do so, FDA's ability to perform its other agency functions, including responding to other document requests, could be impaired.

Pursuant to 28 U.S.C. § 1746, I declare under the penalty of perjury that the foregoing is true and correct.

Executed on December 13, 2021, in Rockville, Maryland.

Sarah B. Kotler -S

Digitally signed by Sarah B. Kotler -S
Date: 2021.12.13 08:47:00 -05'00'

SARAH B. KOTLER
Director of Division of Freedom of Information
Office of the Executive Secretariat
Food and Drug Administration
U.S. Department of Health and Human Services

KOTLER DECLARTION
EXHIBIT A

Comirnaty and Pfizer-BioNTech COVID-19 Vaccine

November 19, 2021: **FDA expands eligibility for COVID-19 vaccine boosters to vaccine recipients 18 and older** after completion of primary vaccination. Read more... (/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-covid-19-vaccine-boosters)

October 29, 2021: **FDA expands emergency use authorization of the Pfizer-BioNTech COVID-19 Vaccine** to **include children 5 through 11 years of age.** Read the press release (/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age) and watch the press conference (https://youtu.be/WLbGnS-kqTY) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Comirnaty Information

Pfizer-BioNTech Fact Sheets

Pfizer-BioNTech Fact Sheet Translations

Información sobre las vacunas para el COVID-19 (https://www.fda.gov/about-fda/fda-en-espanol/informacion-sobre-las-vacunas-para-el-covid-19)

On August 23, 2021, FDA announced the first approval of a COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty, for the prevention of COVID-19 in individuals 16 years of age and older.

Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use and is available under the EUA as a two-dose primary series in individuals 5 years of age and older, as a third primary series dose for individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise, and as a single booster dose in people 18 years of age and older.

The Pfizer-BioNTech COVID-19 Vaccine is also authorized for use as a heterologous (or “mix and match”) booster dose following completion of primary vaccination with a different available COVID-19 vaccine. For example, Moderna and Janssen COVID-19 vaccine recipients 18 years of age and older may receive a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine.

On November 17, 2021, CDC, in consultation with FDA, issued emergency use instructions (https://www.cdc.gov/vaccines/covid-19/eui/index.html) to provide information about the use of the vaccine as an additional primary series dose or as a booster dose in certain individuals (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#people-vaccinated-outside-us) who completed vaccination with certain non-FDA-authorized or -approved COVID-19 vaccines.

Comirnaty (/vaccines-blood-biologics/comirnaty) Information

Information	Last Updated
Package Insert (/media/151707/download)	August 23, 2021
Summary Basis for Regulatory Action (https://www.fda.gov/media/151733/download)	November 8, 2021

Information	Last Updated
Approval Letter (https://www.fda.gov/media/151710/download)	August 23, 2021
FAQ for Comirnaty (COVID-19 Vaccine mRNA) (/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna) (Español (/vaccines-blood-biologics/preguntas-y-respuestas-sobre-comirnaty-vacuna-de-arnm-contra-el-covid-19))	October 20, 2021
CDC-issued Emergency Use Instructions (https://www.cdc.gov/vaccines/covid-19/eui/index.html)	November 17, 2021

Pfizer-BioNTech Fact Sheets (English) and FAQs

Fact Sheet / FAQs	Vaccine Recipient Group	Last Updated
For Healthcare Providers (/media/153713/download)	12 years of age and older, purple cap (must dilute)	November 19, 2021
For Healthcare Providers (/media/153715/download)	12 years of age and older, gray cap (no dilution) *This formulation is not yet available in the United States.*	November 19, 2021
For Healthcare Providers (/media/153714/download)	5 - 11 years of age, orange cap (must dilute)	October 29, 2021
For Recipients and Caregivers (/media/153716/download)	12 years of age and older	November 19, 2021
For Recipients and Caregivers (/media/153717/download)	5 - 11 years of age	October 29, 2021
Frequently Asked Questions on the Pfizer-BioNTech COVID-19 Vaccine (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine-frequently-asked-questions)	All	November 4, 2021

Pfizer-BioNTech Regulatory Information

Information	Date
Decision Memorandum Addendum (/media/154358/download)	November 19, 2021
Decision Memorandum (/media/154357/download)	November 19, 2021
Letter of Authorization (Reissued) (/media/150386/download)	November 19, 2021
Decision Memorandum (/media/153947/download)	October 29, 2021
Advisory Committee Meeting Information (/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-26-2021-meeting-announcement)	October 26, 2021
Decision Memorandum (/media/153482/download)	October 20, 2021
Decision Memorandum (/media/152432/download)	September 24, 2021
Advisory Committee Meeting Information (/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-september-17-2021-meeting-announcement)	September 17, 2021

Information	Date
Concurrence Letter (/media/151731/download)	August 22, 2021
Decision Memorandum (https://www.fda.gov/media/151613/download)	August 12, 2021
Letter Granting EUA Amendment (https://www.fda.gov/media/148877/download)	May 19, 2021
FDA Decision Memorandum (/media/148542/download)	May 10, 2021
Letter Granting EUA Amendment (/media/147390/download)	April 6, 2021
Letter Granting EUA Amendment (/media/145493/download)	January 22, 2021
Letter Granting EUA Amendment (/media/144955/download)	January 6, 2021
FDA Decision Memorandum (/media/144416/download)	December 11, 2020
Advisory Committee Meeting Information (/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement)	December 10, 2020

Media Materials and Webcasts

Information	Date
Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-covid-19-vaccine-boosters)	November 19, 2021
Press Release (/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age)	October 29, 2021
Press Conference (https://youtu.be/WLbGnS-kqTY) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	October 29, 2021
Advisory Committee Webcast (https://youtu.be/laaL0_xKmmA) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	October 26, 2021
Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines)	October 20, 2021
Media Call (https://youtu.be/rou7tf4vaUU) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	October 20, 2021
Press Release (/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations)	September 22, 2021
Advisory Committee Webcast (https://youtu.be/WFph7-6t34M) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	September 17, 2021
Press Release (/news-events/press-announcements/fda-approves-first-covid-19-vaccine)	August 23, 2021
Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised)	August 12, 2021
FDA In Brief (/news-events/press-announcements/fda-brief-fda-authorizes-longer-time-refrigerator-storage-thawed-pfizer-biontech-covid-19-vaccine)	May 19, 2021
Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use)	May 10, 2021

Information	Date
Press Conference (https://youtu.be/npjhwpConSw) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	May 10, 2021
Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-allows-more-flexible-storage-transportation-conditions-pfizer)	February 25, 2021
Press Release (/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19)	December 11, 2020
Press Conference (https://youtu.be/L0K3RsIZIP0) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	December 11, 2020
Advisory Committee Webcast (https://youtu.be/owveMJBTc2I) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	December 10, 2020

Translations of the Pfizer-BioNTech Fact Sheet for Recipients and Caregivers

Fact Sheet	Vaccine Recipient Group	Language
HOJA INFORMATIVA DE VACUNAS PARA RECEPTORES Y CUIDADORES SOBRE LA VACUNA DE PFIZER-BIONTECH CONTRA EL COVID-19 PARA PREVENIR LA ENFERMEDAD DEL CORONAVIRUS 2019 (COVID-19) PARA USO EN PERSONAS DE 5 A 11 AÑOS (/media/153829/download) (October 29, 2021)	5 - 11 years of age	Español (Spanish)
HOJA INFORMATIVA DE VACUNAS PARA RECEPTORES Y CUIDADORES SOBRE COMIRNATY (VACUNA DE ARNm CONTRA EL COVID-19) Y LA VACUNA DE PFIZER-BIONTECH CONTRA EL COVID-19 PARA PREVENIR LA ENFERMEDAD DEL CORONAVIRUS 2019 (COVID-19) PARA USO EN PERSONAS DE 12 AÑOS O MÁS (/media/144625/download) (October 29, 2021)	12 years of age and older (/media/144615/download)	Español (Spanish) (/media/144615/download)
为接种者和护理者提供的关于用于预防2019新冠肺炎（COVID-19）的辉瑞生物技术公司2019新冠肺炎疫苗以个人使用的信息概况说明书 5岁至11岁 (/media/154061/download) (October 29, 2021)	5 - 11 years of age	中文 (Chinese, Simplified)
关于复必泰 (2019核糖核酸新冠肺炎疫苗)以及辉瑞-BioNTech2019新冠肺炎疫苗预防2019新冠肺炎的接受者和护理者须知 (/media/144615/download) (October 29, 2021)	12 years of age and older	中文 (Chinese, Simplified)
برگه حاوی اطلاعات ومعلومات برای متقاضیان و مسؤلین بهداشتی در مورد تطبیق واکسین کووید 19 مرض شیوع یافتهء سال 2019 در میان افرادیکه در سنین PFIZER-BIONTECH 5. الی 11 سال قرار دارند (/media/153840/download) (October 29, 2021)	5 - 11 years of age	دری (Dari)
صفحه معلومات واکسین برای دریافت کننده گان و مراقبت کننده گان در مورد کومیرنتی (واکسین کووید -۱۹، ام ار ان ای) و واکسین کووید-۱۹فایزر-بیو ان تک برای جلوگیری از مرض ویروس کرونا ۲۰۱۹(کووید-۱۹) (/media/153840/download) (October 29, 2021)	12 years of age and older	دری (Dari)

Fact Sheet	Vaccine Recipient Group	Language
FYÈ ENFÒMASYON SOU VAKSEN POU RECIPÈ AK MOUN K'AP PRAN SWEN SANTE SOU VAKSEN PFIZER-BIONTECH COVID-19 POU ANPECHE MALADI CORONAVIRUS 2019 (COVID-19) POU ITILIZE NAN MOUN KI GEN 5 AN RIVE 11 AN DE LAJ (/media/154063/download) (October 29, 2021)	5 - 11 years of age	Kreyòl Ayisyen (Haitian Creole)
FYÈ ENFÒMASYON SOU VAKSEN POU RECIPÈ AK MOUN K'AP PRAN SWEN SANTE SOU COMIRNATY (VAKSEN POU COVID-19, mRNA) AK VAKSEN PFIZER-BIONTECH COVID-19 POU ANPECHE MALADI CORONAVIRUS 2019 (COVID-19) (/media/144618/download) (October 29, 2021)	12 years of age and older	Kreyòl Ayisyen (Haitian Creole)
DAIM NTAWV QHIA TSEEB TXOG TSHUAJ TIV THAIV KAB MOB RAU COV NEEG TAU TXAIS KEV PAB THIAB COV NEEG ZOV TU TXOG QHOV TSHUAJ TIV THAIV KAB MOB COVID-19 PFIZER-BIONTECH LOS TIV THAIV TUS KAB MOB CORONAVIRUS 2019 (COVID-19) NTAWM COV TIB NEEGHNUB NYOOG 5 TXOG 11 XYOOS (/media/154064/download) (October 29, 2021)	5 - 11 years of age	Hmoob (Hmong)
DAIM NTAWV QHIA TSEEB RAU COV NEEG TAU TXAIS KEV PAB THIAB COV NEEG ZOV TU TXOG COMIRNATY (TSHUAJ TIV THAIV KAB MOB COVID-19, mRNA) THIAB QHOV TSHUAJ TIV THAIV KAB MOB COVID-19 PFIZER-BIONTECH LOS TIV THAIV TUS KAB MOB CORONAVIRUS 2019 (COVID-19) (/media/144653/download) (October 29, 2021)	12 years of age and older	Hmoob (Hmong)
បញ្ជីហេតុការណ៍ព័ត៌មានវ៉ាក់សាំងសម្រមាប់អ្នកទទួល និងអ្នកថែរទាំអ្ន◌ា◌ំពីវ៉ាក់សាំងេវី◌េសី បយូទិចកូវីដ19 (PFIZER-BIONTECH COVID-19)ហដើម្បីបង្ការជម្ងឺកូវីដ-19(COVID-19) សម្រមាប់ហម្របើម្រាស់ជាមុ◌្ូយបុគ្គលថដលមានអាយុចាប់ពី 5 ដល់11 ឆ្នាំ (/media/154065/download) (October 29, 2021)	5 - 11 years of age	ភាសាអង់គ្លេស (Khmer)
╝ŢĿÓńĦ⌡ΛþŠ∩ώ╫Γ⌡ó► ╘□oÝψĠθ·ė♣►╝ψĴ╙ý┴┴P♫╘΄·Ĵ╙Ýí└♠‖θ ĵθ╫Ó□oÝψĠθ· COMIRNATY (COVID-19 VACCINE, mRNA) ╘΄·Ħ%ZĦĜZ ╝○O┴΄ĎÝΞ″Yź19 (PFIZER-BIONTECH COVID-19) ńźX■╞Ó╝Aý♠ľ■ĂZÝΞ″Yź-19(COVID-19) (/media/144760/download) (October 29, 2021)	12 years of age and older	ភាសាអង់គ្លេស (Khmer)
5 세에서 11 세에 해당하는사람들에게 코로나바이러스감염증 2019 (COVID-19)를 예방하기 위한화이저 (PFIZER)-바이오엔텍 (BIONTECH) 코비드-19 백신에 대한 환자와 의료진을 위한 백신 정보지 (/media/154076/download) (October 29, 2021)	5 - 11 years of age	한국어 (Korean)
코로나바이러스감염증 2019 (COVID-19)를 예방하기 위한 코멀나티 (코비드-19 백신, 메신저 RNA)와 화이저 (PFIZER)-바이오엔텍 (BIONTECH) 코비드-19 백신에 대한 환자와 의료진을 위한 백신 정보지 (/media/144620/download) (October 29, 2021)	12 years of age and older	한국어 (Korean)

App136

Fact Sheet	Vaccine Recipient Group	Language
او تروکلن ۵ه ل ي اوکنووک هنملراي او يکنووتن اخيسي سکد وا هن په اړي سکوا د هرايل پوينخ) م۱۹د-يووک(وغيړان -PFIZER (PFIZER-BIONTECH COVID-19) سروي و۱۹ويډ-وک کال د۲۰۱۹ي د ک وناسک پروب ونکل ۱۱ نهاب تقيي حقن اموي معلنو نران د کي سک وا۱۹ويډ-وکBI (/media/154106/download)	5 - 11 years of age	Pashto
(October 20, 2021)		
FICHA INFORMATIVA PARA DESTINATÁRIOS CUIDADORES SOBRE A VACINA PFIZER-BIONTECH COVID-19 PARA PREVENIR A DOENÇA DO CORONAVÍRUS 2019 (COVID-19) PARA USO EM INDIVÍDUOS DE 5 A 11 ANOS DE IDADE (/media/154056/download)	5 - 11 years of age	Português (Portuguese)
(October 29, 2021)		
FICHA INFORMATIVA PARA DESTINATÁRIOS E CUIDADORES SOBRE COMIRNATY (COVID-19 VACINA, mRNA) E VACINA PFIZER-BIONTECH COVID-19 PARA PREVENIR A DOENÇA DO CORONAVÍRUS 2019 (COVID-19) (/media/144623/download)	12 years of age and older	Português (Portuguese)
(October 29, 2021)		
ИНФОРМАЦИОННЫЙ БЮЛЛЕТЕНЬ ДЛЯ РЕЦИПИЕНТОВ И СПЕЦИАЛИСТОВ ПО УХОДУ О ВАКЦИНЕ PFIZER-BIONTECH COVID-19 ДЛЯ ПРЕДОТВРАЩЕНИЯ ЗАБОЛЕВАНИЯ КОРОНАВИРУСНОЙ ИНФЕКЦИЕЙ 2019 (COVID-19) У ЛИЦ В ВОЗРАСТЕ ОТ 5 ДО 11 ЛЕТ (/media/154069/download)	5 - 11 years of age	Русский (Russian)
(October 29, 2021)		
ИНФОРМАЦИОННЫЙ БЮЛЛЕТЕНЬ ДЛЯ РЕЦИПИЕНТОВ И СПЕЦИАЛИСТОВ ПО УХОДУ О ВАКЦИНАХ COMIRNATY (мРНК-ВАКЦИНЕ ПРОТИВ COVID-19) И ВАКЦИНЕ PFIZER-BIONTECH COVID-19 ДЛЯ ПРЕДОТВРАЩЕНИЯ ЗАБОЛЕВАНИЯ КОРОНАВИРУСНОЙ ИНФЕКЦИЕЙ 2019 (COVID-19) (/media/144624/download)	12 years of age and older	Русский (Russian)
(October 29, 2021)		
BAKUNA IMPORMASYON FACT SHEET PARA SA MGA TUMANGGAP AT MGA TAGAPAG-ALAGA TUNGKOL SA PFIZER-BIONTECH COVID-19 BAKUNA UPANG MAIWASAN ANG CORONAVIRUS DISEASE 2019 (COVID-19) PARA SA PAGGAMIT SA MGA INDIBIDWAL 5 HANGGANG 11 TAONG GULANG (/media/154071/download)	5 - 11 years of age	Tagalog (Tagalog)
(October 29, 2021)		
FACT SHEET NG IMPORMASYON SA BAKUNA PARA SA MGA TANGGAP AT CAREGIVERS TUNGKOL SA COMIRNATY (COVID-19 VACCINE, mRNA)AT BAKUNA NA PFIZER-BIONTECH COVID-19 UPANG MAIWASAN ANG CORONAVIRUS DISEASE 2019 (COVID-19) (/media/144663/download)	12 years of age and older	Tagalog (Tagalog)
(October 29, 2021)		
BẢNG THÔNG TIN VỀ VẮC XIN DÀNH CHO NGƯỜI NHẬN VÀ NGƯỜI CHĂM SÓC VỀ VẮC XIN PFIZER-BIONTECH COVID-19 NHẰM PHÒNG NGỪA BỆNH CORONAVIRUS 2019 (COVID-19) ĐỂ SỬ DUNG CHO CÁ NHÂN TỪ 5 TỚI 11 TUỔI (/media/154074/download)	5 -11 years of age	Tiếng Việt (Vietnamese)
(October 29, 2021)		

Fact Sheet	Vaccine Recipient Group	Language
TỜ DỮ KIỆN THÔNG TIN VỀ VẮC XIN DÀNH CHO NGƯỜI NHẬN VÀ NGƯỜI CHĂM SÓC VỀ COMIRNATY (VẮC XIN COVID-19, mRNA)VÀ VẮC XIN PFIZER-BIONTECH COVID-19 ĐỂ PHÒNG NGỪA BỆNH CORONAVIRUS 2019 (COVID-19) (/media/144626/download) (October 29, 2021)	12 years of age and older	Tiếng Việt (Vietnamese)
2019-YIL KORONAVIRUS KASALLIGINING (COVID-19) OLDINI OLINISH UCHUN PFIZER-BIONTECH COVID-19 VAKSINA HAQIDA UNI OLUVCHILAR VA ULARNI PARVARISHLAYDIGAN SHAXSLAR UCHUN VAKSINA HAQIDA MA'LUMOTLAR VARAKASI 5 DAN 11 YOSHGACHA (/media/153841/download) (October 29, 2021)	5 -11 years of age	O'zbek (Uzbek)
QABUL QILUVCHILAR VA PARVARISH QILUVCHILAR UCHUN COMIRNATY (COVID-19 Vaksina, mRNA) VA PFIZER-BIONTECH COVID-19 VAKSINASI KORONAVIRUS 2019 (COVID-19) KASALLIGINI OLDINI OLISH UCHUN Vaksina HAQIDA MA`LUMOT VARAQASI (/media/153841/download) (October 29, 2021)	12 years of age and older	O'zbek (Uzbek)

EXHIBIT E

Konkoly, Antonia (CIV)

From: Aaron Siri <aaron@sirillp.com>
Sent: Wednesday, December 8, 2021 4:23 PM
To: Enlow, Courtney D. (CIV)
Cc: Elizabeth Brehm; Gabrielle Palmer
Subject: [EXTERNAL] RE: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good afternoon, Courtney,

Thank you for the response. Four hopefully simple questions/requests:

1. You claim it would take 1.5 days to determine the number of lines in the 126 data files, each similar to a spreadsheet. That estimate is difficult to understand since I would imagine it would require no more than someone opening each file, recording the total number of lines for each one, and then adding up the total number of lines. A paralegal at our firm could accomplish that task in less than an hour. Please explain why it would take 1.5 days to open each file and record the total number of lines in each file?

2. For the data files, please provide the column headers. My client would like to see these to determine if there is anything that can be streamlined.

3. Please provide a more precise number for the category you indicated has "tens of thousands of additional pages."

4. Would the FDA be interested in hiring qualified unpaid volunteers to assist with reviewing the documents requested by PHMPT?

Best regards,
Aaron

From: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Sent: Thursday, December 2, 2021 2:25 PM
To: Aaron Siri <aaron@sirillp.com>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Subject: RE: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good afternoon Aaron,

With regard to your first two questions, FDA will not be able to make those assessments at this time. In order for FDA to determine (1) the number of lines of spreadsheet data or (2) the total number of pages for each line of the 87-page Index, FDA would need to perform a search by hand. In other words, an individual would have to click open each file listed on the 87-page Index to determine the size of the file, and then manually record the file's size. To perform that search for the number of lines of spreadsheet data, FDA estimates that it would take 1.5 days of a staff member's time; to provide the page counts for each entry in the Index, FDA estimates that it would take several days of a staff member's time. Due to the heavy burden such an effort would place on FDA's limited resources, it is not feasible for FDA to provide those estimates.

With regard to your third question, are you asking whether there is any data in the Comirnaty biological product file that are not accounted for in the Index or the estimated 329,000+ page count? If so, the Cominarty biological product file also contains supplements, amendments, and product correspondence. FDA estimates that there are approximately

39,000 pages of records in that category. In addition, there may be investigational new drug records that may be supportive of the BLA. Although FDA cannot provide a precise count at this time, FDA estimates that there would be tens of thousands of additional pages in this category. These page counts are in addition to FDA's estimate of 329,000+ pages (plus data files) in the original Cominarty BLA.

If Plaintiff is amenable to the schedule I proposed yesterday, please let me know this week so that we can inform the Court.

Thanks,
Courtney

Courtney Enlow
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
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(202) 616-8467
courtney.d.enlow@usdoj.gov

From: Aaron Siri <aaron@sirillp.com>
Sent: Wednesday, December 01, 2021 5:56 PM
To: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Subject: [EXTERNAL] RE: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good afternoon Courtney,

Thank you for the note. In order for me to have a meaningful conversation with my client, can you please let me know (1) approximately how many lines of spreadsheet data would need to be processed, (2) the approximate total number of pages for each line item in the Index of Comirnaty BLA you previously provided (copy attached) and (3) what else is in the biological product file for Comirnaty that is not reflected in the attached and is that included in the estimated 329,000 page count (and if not, how many pages does that consist of).

Thank you,
Aaron

From: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Sent: Wednesday, December 1, 2021 8:35 AM
To: Aaron Siri <aaron@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>
Subject: RE: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good morning Aaron,

With regard to *PHMPT v. FDA*, No. 21-cv-1058 (N.D. Tex.), FDA has now had the opportunity to assess the number of responsive pages and to estimate processing times for additional portions of Plaintiff's priority list. In light of that assessment, FDA proposes that it produce the non-exempt portions of the following records by the below dates:

- By December 13, 2021, FDA plans to produce publicly releasable information from:
    - ***Plaintiff's priority item #1***- CRF files for site 1055 (~2,030 pages);
    - ***Completion of Plaintiff's priority item #5***-
        - Four additional .txt files that were listed on p. 10 of the index;
        - Four additional SAS files (not specifically listed on Plaintiff's priority list, but mentioned as something Plaintiff was interested in).
    - Publicly releasable information from the following additional sections of the original Comirnaty BLA:
        - Section 2.5 – Clinical Overview (~333 pages)
        - Section 2.7.3 – Summary of Clinical Efficacy (~182 pages)
        - Section 2.7.4 – Summary of Clinical Safety (~344 pages)
- By December 30, 2021, FDA plans to produce publicly releasable information from ***Plaintiff's priority item #2*** – CRF files for site 1081 (~3,380 pages);
- By January 18, 2022, FDA plans to produce publicly releasable information from ***Plaintiff's priority item #3*** – CRF files for site 1096 (~2,937 pages); and
- By January 31, 2022, FDA plans to produce publicly releasable information from ***Plaintiff's priority item #4*** – CRF files for site 1128 (~3,452 pages).

Under this schedule, by the end of January 2022, FDA expects to have produced publicly releasable information from more than 12,000 pages of records and 10 unpaginated .txt or SAS data files. (This page and file count includes records produced to Plaintiff on November 17, 2021, and records that will be produced to Plaintiff later today.) FDA will also have completed production of seven of the first eight items on the priority list Plaintiff provided to FDA on November 4, 2021.

After the January 31, 2022 production, FDA proposes to make one production at the end of each subsequent month totaling a minimum the non-exempt portions of 500 pages. (For purposes of calculating a "page count" of data records that are not paginated, FDA proposes considering twenty lines of spreadsheet data the equivalent of one page. For example, production of a spreadsheet containing 2,000 lines of data would be counted the equivalent of a 100-page PDF record.) To the extent feasible, FDA plans to continue to prioritize records from Plaintiff's priority list. Although FDA proposes a minimum rate of 500 pages a month, FDA will continue to produce records at a faster rate where feasible.

Please let me know if Plaintiff is amenable to this proposed schedule. If so, I propose that the parties file a joint status report setting out the agreed-upon schedule and requesting that the Court cancel the hearing set for December 14 and the briefing deadlines.

Thanks,
Courtney

Courtney Enlow
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From: Enlow, Courtney D. (CIV)
Sent: Wednesday, November 17, 2021 1:40 PM
To: Aaron Siri <aaron@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>
Subject: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good afternoon Aaron and Gabrielle,

I've attached correspondence from FDA and a release of records in *PHMPT v. FDA*, No. 21-cv-1058 (N.D. Tex.). Kindly confirm receipt.

Thanks,
Courtney

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EXHIBIT F

Konkoly, Antonia (CIV)

From: Konkoly, Antonia (CIV)
Sent: Friday, December 10, 2021 8:57 PM
To: Aaron Siri; Elizabeth Brehm; Gabrielle Palmer
Cc: Enlow, Courtney D. (CIV)
Subject: PHMPT -- conferral questions

Hi Aaron et al –

I assume you saw the NOA that I entered earlier this week; I'm a colleague of Courtney's and will be handling the hearing on Tuesday. I look forward to working with you. We've conferred with FDA regarding the various questions you've posed; please see below the agency's responses, in red.

1.) **You claim it would take 1.5 days to determine the number of lines in the 126 data files, each similar to a spreadsheet. That estimate is difficult to understand since I would imagine it would require no more than someone opening each file, recording the total number of lines for each one, and then adding up the total number of lines. A paralegal at our firm could accomplish that task in less than an hour. Please explain why it would take 1.5 days to open each file and record the total number of lines in each file?**

   - First, FDA derived the number 126 came from its search of a specific portion of the BLA file (within Section 5). However, FDA expects that there are data files in other sections of the application, so 126 is likely not the full number of SAS files for the entire BLA. Accordingly, some the time estimate accounts for the time that would be needed to search for and locate other files. Additionally, SAS files are large and can present technical difficulties for FDA staff to open and navigate. Both search time and expected technical difficulties are thus accounted for in the 1.5 day estimate.

2.) **For the data files, please provide the column headers. My client would like to see these to determine if there is anything that can be streamlined.**

   - Due to the same technical difficulties noted above – which, on the ground, would make this task quite time-consuming – FDA is not able to accommodate this request at this time. In short, the diversion of time this would involve would meaningfully undermine the agency's ability to focus on its processing work.

3.) **Please provide a more precise number for the category you indicated has "tens of thousands of additional pages."**

   - FDA knows that there are a number of records in the IND section of the biological product file; however, it would take a closer review of those pages to determine which information would be considered supportive of the BLA/licensure and, thus, publicly available (subject to disclosure review) under 21 C.F.R. 601.51(e).

     You may already be aware of this, but to make sure we're on the same page – IND files may include studies for several forms (different dose strengths, formulations, etc.) and/or indications (different disease conditions, age groups, etc.). It's possible for a biological product to be approved for only a subset of the variations/indications for which it was originally studied. The portions of the IND file related to the approved conditions would become part of the biological product file that would be available for disclosure (subject to confidentiality review) once the product is approved; portions of the IND related to unapproved forms/indications would remain confidential (as would the existence of these portions).

To be clear, FDA disclosure staff have not yet determined whether portions of the IND section of the Comirnaty file refer to forms or conditions that are have not been approved under a BLA. Thus, this response should not be understood as an indication that any parts of the biological product file relate to INDs associated with a product that has not been approved. But, before performing that review (which would require a substantial investment of time from FDA), we cannot provide a precise page estimate. Because, again, the FDA assesses that that this effort does not justify the diversion of resources away from its processing work, it also cannot accommodate this request at this time.

4.) **Would the FDA be interested in hiring qualified unpaid volunteers to assist with reviewing the documents requested by PHMPT?**

- This is not an option. Non-federal personnel – whether they be unpaid volunteers, or per your later question, persons paid by the Plaintiff – cannot perform federal work.

5.) **Provide a list of the sections of the index that were not disclosed in the PDF index you provided.**

- FDA provided the high-level breakout of the entire original Comirnaty BLA. (See p. 1 of the Index provided on 11-4-21.) However, in accordance with the purpose of the index—ie, to assist PHMPT in honing in on the portions of the BLA that it is most interested in—FDA did not expand the index as to Sections that were not identified by PHMPT's Priority List. Additionally, other sections could not be expanded because to do so could have revealed confidential information.

6.) **An index for the documents in the BLA file that were not included in the index already provided (meaning, an index of the material that was not submitted as part of Comirnaty BLA application). The FOIA request, on its face, was for more than just the Comirnaty BLA submitted by Pfizer.**

- Creating the requested index would require FDA to create screen shots for each section, as it did for the index it provided in November. Given the nature of the documents in these sections, FDA anticipates that there would likely be confidential information in section titles, such that they could not be shared with PHMPT. Again, FDA assess that it cannot reasonably divert resources away from its processing efforts to this task at this time, in light of those circumstances.

Thanks,
Toni

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