

FREEDOM OF INFORMATION ACT REQUEST
EXPEDITED PROCESSING REQUESTED

VIA ONLINE PORTAL

September 14, 2021

Food and Drug Administration
Division of Freedom of Information
Office of the Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: *Ingredients in Pfizer Vaccine (IR#0558)*

Dear Sir or Madam:

This firm represents the Informed Consent Action Network (“ICAN”).

On August 23, 2021, the Food and Drug Administration (“FDA”) approved the Pfizer-BioNTech COVID-19 Vaccine, Comirnaty (the “Pfizer Vaccine”). On behalf of ICAN, please provide the following records to foia@sirillp.com in electronic form:

Please provide a copy of page 8 of the document available at <https://www.fda.gov/media/151733/download>, without any redaction of the ingredients listed at the top of that page. For the avoidance of doubt, the redactions that this request seeks to lift are as follows:

Ingredients	Quantity after Dilution (per vial)	Function
(UNII: 451W47IQ8X)		
Dibasic sodium phosphate dihydrate (UNII: GR686LBA74)	0.49 mg	Excipient
Sucrose (UNII: C151H8M554)	46.0 mg	Excipient
(b) (4) (UNII: (b) (4))	0.450 mL	Excipient

UNII: Unique Ingredient Identifier

ICAN requests expedited processing for this request. ICAN is “primarily engaged in disseminating information to the general public” and there is an “urgency to inform the public concerning actual or alleged Federal Government activity.” 5 U.S.C. § 552(a)(6)(E)(v)(II). Specifically, ICAN’s mission is to raise public awareness about public health and safety and to

provide the public with information to give informed consent regarding related health interventions and precautions. As part of its mission, ICAN disseminates information to an audience of approximately 5 million people.

The FDA “is responsible for protecting public health by ensuring the safety[] [and] efficacy . . . of . . . biological products[.]”¹ As part of that responsibility, the FDA approves drugs and biologics, typically, before they become available to the public.² Congress mandated that the FDA only approve a product if its sponsor has proven it to be “safe and effective.” *See, e.g.*, 21 U.S.C. § 393.

The FDA claims that it is committed to “open[ing] the doors of the agency.” In that regard, it maintains an entire section on its website dedicated to transparency.³ However, in approving the Pfizer Vaccine for individuals 16 years of age and older, the FDA refused to release much of the information necessary to inform the public as to the composition of the Pfizer Vaccine, including the names of certain ingredients and their unique ingredient identifier (UNII).⁴ This information is a matter of current exigency to the American public for two reasons.

First, there is an ongoing, public national debate regarding the adequacy of the data and information, and analyses of same, relied upon by the FDA to license the Pfizer Vaccine. On the one hand, there are numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms that have declared that the data and information underlying the licensure of the Pfizer Vaccine is more than sufficient for licensure.

For example, in a press release issued on August 23, 2021, acting FDA Commissioner Janet Woodcock stated that “the public can be very confident that [the Pfizer Vaccine] meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product.”⁵ Peter Marks, the director of FDA’s Center for Biologics Evaluation and Research, made similar remarks, stating that

[The FDA’s] scientific and medical experts conducted an incredibly thorough and thoughtful evaluation of [the Pfizer Vaccine]. We evaluated scientific data and information included in hundreds of thousands of pages, conducted our own analyses of [the Pfizer Vaccine’s] safety and effectiveness, and performed a detailed assessment of the manufacturing

¹ <https://www.fda.gov/about-fda/what-we-do> (last visited 8/25/2021).

² <https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved> (last visited 8/23/2021).

³ <https://www.fda.gov/about-fda/transparency> (last visited 9/14/2021).

⁴ <https://www.fda.gov/media/151733/download> (last visited 9/14/2021).

⁵ <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine> (last visited 9/8/2021).

processes, including inspections of the manufacturing facilities[.]⁶

Peter Marks further stated that “although [the FDA] approved [the Pfizer Vaccine] expeditiously, it was fully in keeping with [the FDA’s] existing high standards for vaccines in the U.S.”⁷ President Biden also stated that the FDA’s approval meets the “gold standard.”⁸ Even prior to FDA approval of the Pfizer Vaccine, government officials, public health authorities, and medical professionals repeatedly claimed that COVID-19 vaccines are “safe and effective.”⁹

On the other hand, numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, adequacy of the review, and appropriateness of the analyses relied upon to license the Pfizer Vaccine. For example, on June 1, 2021, a group of 27 clinicians and scientists filed a Citizen Petition¹⁰ with the FDA, claiming that the available evidence for licensure of the Pfizer Vaccine “is simply not mature enough at this point to adequately judge whether clinical benefits outweigh the risks in all populations.”¹¹

Peter Doshi has publicly questioned the lack of transparency regarding the vaccine approval process,¹² which Peter Marks publicly disputed.¹³ Peter Doshi has also questioned the adequacy of the data on the basis that the Pfizer Vaccine is only “13 months into the still ongoing, two year pivotal trial, with no reported data past 13 March 2020, unclear efficacy after six months

⁶ *Id.*

⁷ *Id.*

⁸ <https://www.cbsnews.com/news/biden-address-covid-19-vaccine-pfizer-fda-approval-watch-live-stream-today-2021-08-23/> (last visited 9/8/2021).

⁹ See, e.g., <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html#:~:text=COVID%2D19%20vaccines%20are%20safe,vaccine%20as%20soon%20as%20possible>. (last visited 9/8/2021). See also <https://www.hhs.gov/> (“COVID-19 vaccines are safe, effective, and free”) (last visited 9/8/2021); <https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection> (“COVID-19 vaccines have proven to be safe, effective and life-saving.”) (last visited 9/8/2021); <https://www.doh.wa.gov/Emergencies/COVID19/VaccineInformation/SafetyandEffectiveness> (“COVID-19 vaccines are safe”) (last visited 9/8/2021); <https://www.wlns.com/news/gov-whitmer-and-dr-khaldun-respond-to-the-fda-approval-of-pfizers-covid-19-vaccine/> (quoting Governor Whitmer referring to the Pfizer Vaccine as a “safe, effective COVID-19 vaccine”) (last visited 9/8/2021).

¹⁰ <https://www.regulations.gov/document/FDA-2021-P-0521-0001> (last visited 9/8/2021).

¹¹ See <https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/> (last visited 9/8/2021).

¹² See <https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/> (last visited 9/8/2021); <https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/> (last visited 9/8/2021); <https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/> (last visited 9/8/2021).

¹³ <https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-pfizer-biontech-vaccine/> (last visited 9/8/2021).

due to unblinding, evidence of waning protection irrespective of the Delta variant, and limited reporting of safety data.”¹⁴

Andrew Kheriaty, professor of psychiatry at UCI School of Medicine, Director of the Medical Ethics Program at UCI Health,¹⁵ has also questioned the FDA’s approval process. For example, in an article published in the Wall Street Journal, Dr. Kheriaty questioned the need for student vaccination requirements based on, among other things, a review¹⁶ by the FDA’s Vaccines and Related Biological Products Advisory Committee (“VRBPAC”) that indicates a risk of heart inflammation after vaccination.¹⁷

Government officials have raised similar concerns about the lack of transparency in the review process, arguing that it is “essential” for the FDA to, among other things, “make the data generated by clinical trials and supporting documents submitted to the FDA by developers available to the public[.]”¹⁸ Despite all eyes on the COVID-19 vaccines and calls for transparency regarding the FDA’s actions, the FDA did not convene its advisory group, VRBPAC, to have a public meeting prior to licensure. Those interested were denied the opportunity to both hear discussion about the data and to offer public comment about same.

The public debate regarding the adequacy of the FDA’s review process and the safety and efficacy of the Pfizer Vaccine is unlikely to be settled without full disclosure of the ingredients in the same.

The second reason that this request is of a matter of current exigency is that the Pfizer Vaccine is being mandated to individuals across the country by the federal government,¹⁹ local

¹⁴ <https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/> (last visited 9/8/2021).

¹⁵ <https://www.aaronkheriaty.com/bio> (last visited 9/8/2021).

¹⁶ <https://www.fda.gov/media/150054/download> (last visited 9/8/2021).

¹⁷ <https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220> (last visited 9/8/2021).

¹⁸ https://www.warren.senate.gov/imo/media/doc/2020.09.14%20Letter%20to%20FDA%20re%20transparency%20in%20vaccine%20review%20process_.pdf (last visited 9/8/2021). *See also* <https://www.washingtontimes.com/news/2021/aug/23/editorial-the-coincidental-timing-of-pfizers-vacci/> (last visited 9/8/2021).

¹⁹ *See, e.g.*, <https://www.natlawreview.com/article/covid-19-vaccine-added-to-requirements-green-card-processing-effective-oct-1> (last visited 9/8/2021); <https://apnews.com/article/business-health-coronavirus-pandemic-coronavirus-vaccine-4cf7451267919302de4a7b591508e80c> (last visited 9/8/2021); <https://www.forbes.com/sites/joewalsh/2021/08/09/us-military-will-require-covid-vaccinations-by-mid-september/?sh=78defacd6c9f> (last visited 9/8/2021); <https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/29/fact-sheet-president-biden-to-announce-new-actions-to-get-more-americans-vaccinated-and-slow-the-spread-of-the-delta-variant/> (last visited 9/8/2021).

governments,²⁰ public and private employers,²¹ universities,²² schools,²³ and various other institutions,²⁴ and many more entities are expected to follow suit.²⁵ At the federal level, legislation was recently introduced that would require COVID-19 vaccines for air travel into or out of the

²⁰ See, e.g., <https://www.cnn.com/2021/08/12/us/san-francisco-vaccine-requirement/index.html> (last visited 9/8/2021); <https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page> (last visited 9/8/2021); <https://news.yahoo.com/orleans-now-requires-proof-vaccination-230433492.html> (last visited 9/8/2021).

²¹ See, e.g., <https://www.cnn.com/2021/08/06/united-airlines-vaccine-mandate-employees.html> (last visited 9/8/2021); <https://sanfrancisco.cbslocal.com/2021/08/02/covid-kaiser-permanente-makes-vaccination-mandatory-for-all-employees/> (last visited 9/8/2021); <https://abcnews.go.com/Health/wireStory/walmart-mandates-vaccines-workers-headquarters-79177220> (last visited 9/8/2021); <https://www.kpbs.org/news/2021/aug/17/encinitas-covid-19-vaccine-negative-test-employees/> (last visited 9/8/2021); <https://www.cnn.com/2021/08/09/covid-vaccine-mandates-sweep-across-corporate-america-as-delta-surges.html> (last visited 9/8/2021); <https://www.reuters.com/business/energy/chevron-begins-covid-19-vaccination-mandates-wsj-2021-08-23/> (last visited 9/8/2021); <https://thehill.com/policy/healthcare/569051-pfizers-full-approval-triggers-new-vaccine-mandates> (last visited 9/8/2021); <https://cvshealth.com/news-and-insights/statements/cvs-health-will-require-covid-19-vaccinations-for-clinical-and-corporate-employees> (last visited 9/8/2021).

²² See <https://universitybusiness.com/state-by-state-look-at-colleges-requiring-vaccines/> (last visited 9/8/2021). See also, e.g., <https://www.nbcnews.com/health/health-news/colleges-universities-covid-vaccination-mandates-facing-pushback-n1273916> (last visited 9/8/2021); <https://www.colorado.edu/covid-19/updates/covid-19-vaccination> (last visited 9/8/2021); <https://uhs.berkeley.edu/requirements/covid19> (last visited 9/8/2021); <https://huhs.harvard.edu/covid-19-vaccine-requirement-faqs> (last visited 9/8/2021); <https://www2.gmu.edu/safe-return-campus/vaccination-requirements> (last visited 9/8/2021); <https://www.pc.pitt.edu/news/vaccine-disclosure-requirements-2021-2022-campus-housing> (last visited 9/8/2021)

²³ See, e.g., <https://www.npr.org/sections/back-to-school-live-updates/2021/08/20/1029837338/a-california-school-district-mandates-vaccines-for-eligible-students> (last visited 9/8/2021); <https://patch.com/massachusetts/salem/salem-school-committee-approves-vaccine-mandate-sports-band> (last visited 9/8/2021); <https://www.nbcnewyork.com/news/coronavirus/nyc-will-require-vaccination-for-high-risk-school-sports/3232745/> (last visited 9/8/2021); <https://www.nj.com/hudson/2021/08/hoboken-believed-to-be-first-in-state-to-issue-mandate-for-students-12-and-up-get-vaccine-or-face-weekly-testing.html> (last visited 9/8/2021); <https://www.mercurynews.com/2021/08/19/la-county-school-district-mandates-covid-vaccines-for-k12-kids-others-soon-may-follow/> (last visited 9/8/2021).

²⁴ See, e.g., <https://www.reuters.com/world/us/new-york-city-mandates-covid-19-vaccine-public-school-teachers-staff-mayor-2021-08-23/> (last visited 9/8/2021); <https://www.cbsnews.com/news/california-covid-vaccine-teachers-mandate/> (last visited 9/8/2021); <https://www.nytimes.com/2021/08/18/us/washington-state-teacher-vaccine-mandate.html> (last visited 9/8/2021); <https://www.governor.ny.gov/news/governor-cuomo-announces-covid-19-vaccination-mandate-healthcare-workers> (last visited 9/8/2021); <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx> (last visited 9/8/2021); <https://www.nytimes.com/2021/08/09/us/washington-state-workers-vaccine-mandate.html> (last visited 9/8/2021); <https://www.denvergov.org/Government/COVID-19-Information/Public-Health-Orders-Response/News-Updates/2021/Mayor-Hancock-Announces-COVID-19-Vaccine-Requirement-for-Employees> (last visited 9/8/2021); See <https://www.bostonherald.com/2021/08/19/baker-issues-vaccine-mandate-for-42000-state-employees/> (last visited 9/8/2021).

²⁵ See <https://www.mississippifreepress.org/15126/fda-fully-approves-pfizer-biontech-vaccine-mandates-to-follow/> (last visited 9/8/2021); https://www.huffpost.com/entry/vaccine-mandates-roll-out-fda-approval_n_6123e028e4b0df3eacd5d657 (last visited 9/8/2021); https://www.theadvocate.com/baton-rouge/news/coronavirus/article_9be6d02c-0434-11ec-b7b1-cb17d8495274.html?utm_medium=social&utm_source=twitternoladotcom&utm_campaign=snd (last visited 9/8/2021). See also <https://www.latimes.com/california/story/2021-08-26/california-lawmakers-grapple-with-statewide-covid-19-vaccine-mandate> (last visited 9/8/2021).

United States²⁶ and the Pentagon has mandated COVID-19 vaccines for all military personnel.²⁷ In addition, Present Biden recently announced vaccine mandates for all employers with 100 or more employees, all federal employees, and all employees of federal contractors.²⁸ At the state level, legislation has been introduced to require COVID-19 vaccines for all post-secondary students,²⁹ all state employees,³⁰ and even for all citizens of the state.³¹ As explained by Dr. Anthony Fauci, “a flood” of vaccine mandates will follow FDA approval of a COVID-19 vaccine³² and President Biden is actively encouraging “companies in the private sector to step up the vaccine requirements[.]”³³ More recently, it appears that mandates may now encompass additional booster shots of the vaccine in order to retain a “fully vaccinated” status.³⁴

Delaying public access to the requested information would compromise a number of significant recognized interests, including ICAN’s right, as a media outlet, to timely contribute to the public’s understanding of the Pfizer Vaccine and the public’s right to have a full understanding of a product being mandated in numerous settings by both governments and private businesses.

²⁶ <https://www.congress.gov/bill/117th-congress/house-bill/4980?q=%7B%22search%22:%5b%224980%252> (last visited 8/23/2021).

²⁷ <https://thehill.com/policy/defense/568996-pentagon-to-mandate-covid-19-vaccine-for-military> (last visited 8/23/2021).

²⁸ <https://www.whitehouse.gov/covidplan/> (last visited 9/13/2021). *See also* <https://www.cnn.com/2021/09/09/politics/joe-biden-covid-speech/index.html> (last visited 9/13/2021).

²⁹ *See* New York bill S6495 available at <https://www.nysenate.gov/legislation/bills/2021/S6495> (last visited 9/8/2021).

³⁰ *See, e.g.,* <https://www.nj.com/coronavirus/2021/08/murphy-orders-vaccination-requirement-for-all-nj-state-workers-including-at-public-colleges.html> (last visited 9/8/2021).

³¹ *See* New York bill A11179 available at <https://www.nysenate.gov/legislation/bills/2019/A11179>. *See generally* <https://eastcountytoday.net/buffy-wicks-transportation-bill-could-become-california-vaccine-passport-bill/> (last visited 9/8/2021).

³² <https://www.usatoday.com/story/news/health/2021/08/06/anthony-fauci-covid-vaccine-mandates-fda-full-approval/5513121001/> (last visited 9/8/2021).

³³ <https://www.msn.com/en-us/news/us/biden-urges-private-companies-to-implement-covid-19-vaccine-requirements-following-pfizer-e2-80-99s-fda-approval/ar-AANEcYs?ocid=uxbndlbing> (last visited 9/8/2021). *See also* <https://www.nytimes.com/2021/08/23/us/pfizer-vaccine-mandates.html> (noting that FDA approval of the Pfizer Vaccine “is opening the way for institutions like the military, corporate employers, hospitals and school districts to announce vaccine mandates for their employees”) (last visited 8/23/2021); <https://www.msn.com/en-us/news/us/now-that-a-covid-19-shot-is-fully-approved-employer-mandates-are-rolling-in-but-will-vaccination-rates-in-the-us-go-up/ar-AANGDTy?ocid=uxbndlbing> (last visited 8/23/2021); <https://news.yahoo.com/surgeon-general-vivek-murthy-says-205530053.html> (quoting the Surgeon General referring to vaccine mandates as “reasonable”) (last visited 8/23/2021).

³⁴ *See* <https://www.nbcnews.com/health/health-news/u-s-announces-plan-offer-boosters-all-americans-starting-late-n1277059> (quoting the U.S. Surgeon General stating “it is our clinical judgment that the time to lay out a plan for Covid-19 boosters is now”) (last visited 9/13/2021); <https://www.youtube.com/watch?v=ciVGAPuruoQ> at 17:21 (video of Rochelle P. Walensky, Director of the CDC, stating “we are planning for Americans to receive booster shots”) (last visited 9/13/2021).

ICAN incorporates all articles and information regarding the COVID-19 pandemic, the Pfizer Vaccine, and the sweeping mandates being implemented across the country as if set forth fully herein.

ICAN certifies that the information in this request is true and correct to the best of its knowledge and belief.

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552 (a)(4)(A)(iii). ICAN is a not-for-profit 501(c)(3) organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. As part of its mission, ICAN actively investigates and disseminates information regarding vaccine safety issues, including through its website, and through press events and releases. ICAN is seeking the information in this FOIA request to allow it to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information ICAN is requesting will not contribute to any commercial activities.

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We, therefore, request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. ICAN of course reserves all rights to appeal the withholding or deletion of any information.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately file an administrative appeal.

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact me at (212) 532-1091 or via email at foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,



Aaron Siri
Elizabeth Brehm
Gabrielle Palmer