Exhibit 1

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FREEDOM OF INFORMATION ACT REQUEST
EXPEDITED PROCESSING REQUESTED

VIA ONLINE PORTAL February 23, 2022

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

Re: Moderna COVID-19 Vaccine Biological Product File (IR#0710)

Dear Sir or Madam:

This firm represents Public Health and Medical Professionals for Transparency ("**PHMPT**").

On January 31, 2022, the Food and Drug Administration ("**FDA**") approved the Moderna[1] COVID-19 Vaccine, marketed as Spikevax (the "**Moderna Vaccine**") for individuals 18 years of age and older. On behalf of PHMPT and its individual members, please provide the following records to foia@sirillp.com in electronic form:

> **All data and information for the Moderna Vaccine enumerated in 21 C.F.R. § 601.51(e)[2] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.[3]**

[1] For purposes of this request, Moderna shall be interpreted to include Moderna, Inc. and any of its parents, subsidiaries and affiliates.

[2] 21 C.F.R. § 601.51(e) provides that after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: "(1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . . (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . . (4) A list of all active ingredients and any inactive ingredients . . . . (5) An assay method or other analytical method . . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . . (7) All records showing the manufacturer's testing of a particular lot . . . . (8) All records showing the testing of and action on a particular lot by the [FDA]."

[3] For the avoidance of doubt, this request includes but is not limited to all of the data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the Moderna Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

I. EXPEDITED PROCESSING REQUESTED

PHMPT requests expedited processing for this request as it meets the requirements for expedited processing under both FDA's FOIA Regulations as well as FOIA itself.

A. PHMPT Qualifies for Expedited Processing Under FOIA

FOIA provides for "expedited processing of requests for records" upon a showing of "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). The requestor shows a "compelling need" when it is "primarily engaged in disseminating information," 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).

Here, PHMPT is an organization made up of public health professionals, medical professionals, scientists, and journalists. PHMPT exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 vaccines. PHMPT intends to make any records produced in response to this FOIA request immediately available to the public through both its website and its individual members' platforms. Many of PHMPT's individual members, including all its members that are journalists, are primarily engaged in disseminating information to the public and do so across various platforms, including through interviews, articles, blogs, essays, and podcasts. Therefore, PHMPT and many of its members are "primarily engaged in disseminating information [] to inform the public," and, as explained below, there is a clear "urgency to inform the public concerning actual or alleged Federal Government activity," which in this case is the data and information underlying the licensure of the Moderna Vaccine. Accordingly, expedited processing of this request under FOIA is warranted.

B. PHMPT Qualifies for Expedited Processing Under the FDA's FOIA Regulations

Notably, separate and apart from the FDA's obligation to comply with FOIA, it has an independent duty to inform the public concerning the data and information underlying a licensed vaccine. The FDA's Regulations expressly provide that "[a]fter a license has been issued, the following data and information in the biological product file are *immediately available* for public disclosure unless extraordinary circumstances are shown: (1) All safety and effectiveness data and information . . ." 21 C.F.R. § 601.51(e)(1) (emphasis added). Thus, the FDA's own regulations expressly recognize the importance of having the data and information relied upon to license a vaccine "immediately available for public disclosure." *Id.* This policy supports the FDA's claimed commitment to,[4] and assurances of, transparency[5] as a lack of transparency erodes the confidence the medical and scientific communities and the public have in the conclusions reached by the FDA. However, the fact that the FDA did not release the documents following licensure necessitated this FOIA request.

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[4] https://www.fda.gov/news-events/press-announcements/covid-19-update-fdas-ongoing-commitment-transparency-covid-19-euas (last visited 2/19/2022).

[5] https://www.fda.gov/about-fda/transparency/transparency-initiative (last visited 2/19/2022); https://www.fda.gov/news-events/speeches-fda-officials/fostering-transparency-improve-public-health (last visited 2/19/2022).

But aside from the FDA's duty to make immediately available the safety and effectiveness data of a licensed vaccine, the FDA's FOIA regulations anticipate scenarios where FOIA requests must be expedited. Specifically, a requestor is entitled to expedited processing where:

> (1) The requester is primarily engaged in disseminating information to the general public and not merely to a narrow interest group;
>
> (2) There is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly; however, a news media publication or broadcast deadline alone does not qualify as an urgent need, nor does a request for historical information; and
>
> (3) The request for records specifically concerns identifiable operations or activities of the Federal Government.

21 C.F.R. § 20.44(c)(1)-(3).

PHMPT easily meets all three requirements. As noted above, PHMPT is an organization made up of public health professionals, medical professionals, scientists, and journalists that was created and exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 vaccines. Therefore, PHMPT is certainly "primarily engaged in disseminating information to the general public." 21 C.F.R. § 20.44(c)(1).

Next, there is plainly an urgent public need for transparency with regard to the data relied upon in licensing the Moderna Vaccine for at least two distinct reasons beyond the FDA's own regulations which admit the urgent need for transparency and disclosure of this information. As required by Congress, the FDA may only license vaccines that have been proven to be "safe and effective," *see, e.g.*, 21 U.S.C. § 393, and the FDA makes this determination based on, *inter alia*, clinical trial reports provided by the sponsor which must be sufficient to demonstrate the product is both "safe" and "effective."[6] 21 C.F.R. 601.2(a). There is, however, 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 COVID-19 vaccines, including the Moderna 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 Moderna Vaccine is more than sufficient for licensure. For example, in a statement released on January 31, 2022, acting FDA Commissioner Janet Woodcock, M.D., stated:

> The public can be assured that Spikevax meets the FDA's high standards for safety, effectiveness and manufacturing quality

[6] The FDA explains in its guidance materials that the clinical trials relied upon for approval are typically "1 to 4 years" (https://www.fda.gov/patients/drug-development-process/step-3-clinical-research) and the duration of clinical trials should "reflect the product and target condition." https://www.fda.gov/media/102332/download (last visited 02/19/2022). *See also* https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved (last visited 02/19/2022); https://www.fda.gov/about-fda/what-we-do (last visited 02/19/2022).

> required of any vaccine approved for use in the United States. While hundreds of millions of doses of Moderna COVID-19 Vaccine have been administered to individuals under emergency use authorization, we understand that for some individuals, FDA approval of this vaccine may instill additional confidence in making the decision to get vaccinated.[7]

Peter Marks, M.D., Ph.D., the director of FDA's Center for Biologics Evaluation and Research, made similar remarks:

> The FDA's medical and scientific experts conducted a thorough evaluation of the scientific data and information included in the application pertaining to the safety, effectiveness, and manufacturing quality of Spikevax. This includes the agency's independent verification of analyses submitted by the company, our own analyses of the data, along with a detailed assessment of the manufacturing processes, test methods and manufacturing facilities . . . Safe and effective vaccines are our best defense against the COVID-19 pandemic, including currently circulating variants. The public can be assured that this vaccine was approved in keeping with the FDA's rigorous scientific standards.[8]

Even prior to FDA approval of the Moderna Vaccine, government officials, public health authorities, and medical professionals repeatedly claimed that COVID-19 vaccines were "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, the adequacy of the review, and appropriateness of the analyses relied upon to license the Moderna Vaccine, including a number of the scientists and journalists that are members of PHMPT. For example, in July 2021, a group of 27 clinicians, scientists, and patient advocates, including PHMPT members Peter Doshi, Ph.D., Senior Editor for The BMJ and Associate Professor of Pharmaceutical Health Services Research at the University of Maryland School of Pharmacy,[10] and Peter A. McCullough, M.D. filed an amended Citizen Petition[11] with the FDA, claiming that the available evidence for licensure of the

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[7] https://www.cnn.com/2022/01/31/health/moderna-covid-vaccine-fda-approval/index.html.

[8] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine.

[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 02/19/2022). *See also* 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 02/19/2022); https://www.doh.wa.gov/Emergencies/COVID19/VaccineInformation/SafetyandEffectiveness ("COVID-19 vaccines are safe") (last visited 02/19/2022).

[10] https://www.bmj.com/about-bmj/editorial-staff/peter-doshi (last visited 02/19/2022).

[11] https://www.regulations.gov/document/FDA-2021-P-0521-0001 (last visited 02/19/2022).

Moderna Vaccine "is simply not mature enough at this point to adequately judge whether clinical benefits outweigh the risks in all populations."[12] Separately, Dr. Doshi has publicly questioned the lack of transparency regarding the vaccine approval process[13] which Dr. Peter Marks publicly disputed.[14] Aaron Kheriaty, M.D., former-Professor of Psychiatry at UCI School of Medicine, former-Director of the Medical Ethics Program at UCI Health,[15] and a member of PHMPT, 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 review[16] by the FDA's Vaccines and Related Biological Products Advisory Committee 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] PHMPT incorporates by reference, as if cited and fully set forth herein, any and all articles, media, and publications regarding or reflecting the public discussion, discourse, and debate regarding the Moderna Vaccine, including all matters related to the licensure of this product.

Given this widespread and ongoing public debate, the medical and scientific communities and the public have an immediate need to review the data and information underlying the licensure of the Moderna Vaccine. Public disclosure of this information will inform this ongoing public debate. Releasing this data should also confirm the FDA's conclusion and thus increase confidence in the safety and efficacy of the Moderna Vaccine.

Secondly, and perhaps even more significantly, there is an urgent need for the public to have immediate access to the data and information underlying the licensure of the Moderna Vaccine because, over the objections of many, this product is being mandated to individuals across

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[12] *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 02/19/2022).

[13] *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 2/19/2022); 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 2/19/2022); 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 02/19/2022).

[14] https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-Pfizer-biontech-vaccine/ (last visited 02/19/2022).

[15] https://www.aaronkheriaty.com/bio (last visited 02/19/2022).

[16] https://www.fda.gov/media/150054/download (last visited 02/19/2022)

[17] https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220 (last visited 02/19/2022).

[18] https://www.warren.senate.gov/imo/media/doc/2020.09.14%20Letter%20to%20FDA%20re%20transparency%20in%20vaccine%20review%20process_.pdf (last visited 02/19/2022).

the country by the federal government,[19] local governments, [20] public and private employers,[21] universities, [22] schools,[23] and various other institutions,[24] and many are expected to follow suit. At the federal level, legislation was introduced that would require COVID-19 vaccines for air travel into or out of the United States,[25] and the Pentagon has mandated the COVID-19 vaccines

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[19] *See, e.g.*, https://www.natlawreview.com/article/covid-19-vaccine-added-to-requirements-green-card-processing-effective-oct-1 (last visited 02/19/2022); https://apnews.com/article/business-health-coronavirus-pandemic-coronavirus-vaccine-4cf7451267919302de4a7b591508e80c (last visited 02/19/2022); https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF (last visited 2/19/2022); 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 02/19/2022).

[20] *See, e.g.*, https://www.cnn.com/2021/08/12/us/san-francisco-vaccine-requirement/index.html (last visited 02/19/2022); https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page (last visited 2/19/2022); https://news.yahoo.com/orleans-now-requires-proof-vaccination-230433492.html (last visited 02/19/2022).

[21] *See, e.g.*, https://www.cnbc.com/2021/08/06/united-airlines-vaccine-mandate-employees.html (last visited 02/19/2022); https://sanfrancisco.cbslocal.com/2021/08/02/covid-kaiser-permanente-makes-vaccination-mandatory-for-all-employees/ (last visited 2/19/2022); https://abcnews.go.com/Health/wireStory/walmart-mandates-vaccines-workers-headquarters-79177220 (last visited 02/19/2022); https://www.kpbs.org/news/2021/aug/17/encinitas-covid-19-vaccine-negative-test-employees/ (last visited 02/19/2022); https://www.cnbc.com/2021/08/09/covid-vaccine-mandates-sweep-across-corporate-america-as-delta-surges.html (last visited 2/19/2022); https://www.reuters.com/business/energy/chevron-begins-covid-19-vaccination-mandates-wsj-2021-08-23/ (last visited 02/19/2022); https://thehill.com/policy/healthcare/569051-Pfizers-full-approval-triggers-new-vaccine-mandates (last visited 02/19/2022); https://cvshealth.com/news-and-insights/statements/cvs-health-will-require-covid-19-vaccinations-for-clinical-and-corporate-employees (last visited 02/19/2022).

[22] *See* (last visited 02/19/2022). *See also, e.g.*, https://www.nbcnews.com/health/health-news/colleges-universities-covid-vaccination-mandates-facing-pushback-n1273916 (last visited 02/19/2022); https://www.colorado.edu/covid-19-updates/covid-19-vaccination (last visited 02/19/2022); https://uhs.berkeley.edu/requirements/covid19 (last visited 02/19/2022); https://huhs.harvard.edu/covid-19-vaccine-requirement-faqs (last visited 02/19/2022); https://www2.gmu.edu/safe-return-campus/vaccination-requirements (last visited 2/07/2022).

[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 2/19/2022); https://patch.com/massachusetts/salem/salem-school-committee-approves-vaccine-mandate-sports-band (last visited 2/19/2022); https://www.nbcnewyork.com/news/coronavirus/nyc-will-require-vaccination-for-high-risk-school-sports/3232745/ (last visited 02/19/2022); 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 02/19/2022); https://www.mercurynews.com/2021/08/19/la-county-school-district-mandates-covid-vaccines-for-k12-kids-others-soon-may-follow/ (last visited 02/19/2022).

[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 02/19/2022); https://www.cbsnews.com/news/california-covid-vaccine-teachers-mandate/ (last visited 02/19/2022); https://www.nytimes.com/2021/08/18/us/washington-state-teacher-vaccine-mandate.html (last visited 02/19/2022); https://www.governor.ny.gov/news/governor-cuomo-announces-covid-19-vaccination-mandate-healthcare-workers (last visited 02/19/2022); https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx (last visited 02/19/2022); https://www.nytimes.com/2021/08/09/us/washington-state-workers-vaccine-mandate.html (last visited 02/19/2022); 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 2/19/2022); *See* https://www.bostonherald.com/2021/08/19/baker-issues-vaccine-mandate-for-42000-state-employees/ (last visited 02/19/2022).

[25] https://www.congress.gov/bill/117th-congress/house-bill/4980?q=%7B%22search%22:%5b%224980%252 (last visited 02/19/2022).

for all military personnel.[26] At the state level, legislation has been introduced to require COVID-19 vaccines for all post-secondary students,[27] all state employees, [28] and even for all citizens of various states.[29] As explained by Dr. Anthony Fauci, "a flood" of vaccine mandates follow FDA approval of a COVID-19 vaccine,[30] and President Biden has actively encouraged "companies in the private sector to step up the vaccine requirements[.]"[31] During a time when COVID-19 vaccine mandates are being implemented over the objection of those that have questions about the data and information supporting the safety and efficacy of the Moderna Vaccine, and individuals with these questions are being expelled from employment, school, transportation, and the military, the public has an urgent and immediate need to have access to this data. The value of this information will be all but useless to these individuals if they are forced to receive a vaccine prior to seeing the data relied upon by the FDA and various institutions mandating approved vaccines. Without immediate access to the data, many of these individuals will forever lose the chance to evaluate the data for themselves and see whether this vaccine is indeed "safe and effective" prior to being mandated to receive it. Having multiple trusted independent authorities, including PHMPT, review the safety and effectiveness data sought in this FOIA request will almost certainly assist these individuals in evaluating their vaccine decisions. Therefore, for all of these reasons, PHMPT has shown there is "an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly." 21 C.F.R. § 20.44(c)(2).

Finally, PHMPT's request meets the third requirement for expedited processing – that "[t]he request for records specifically concerns identifiable operations or activities of the Federal Government." 21 C.F.R. § 20.44(c)(3). Here, PHMPT's records request specifically concerns identifiable activities—i.e., approval of the Moderna Vaccine—by the Federal Government—to wit, the FDA.

In light of the above, PHMPT has demonstrated that its request qualifies for expedited processing under both the FDA's FOIA regulations, as well as FOIA itself. PHMPT incorporates by reference, as if cited and fully set forth herein, any and all articles, media, and publications

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[26] https://thehill.com/policy/defense/568996-pentagon-to-mandate-covid-19-vaccine-for-military (last visited 02/19/2022).

[27] *See* New York bill S6495, available at https://www.nysenate.gov/legislation/bills/2021/S6495 (last visited 02/19/2022).

[28] *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 02/19/2022).

[29] *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 02/19/2022).

[30] https://www.usatoday.com/story/news/health/2021/08/06/anthony-fauci-covid-vaccine-mandates-fda-full-approval/5513121001/ (last visited 2/19/22).

[31] 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 02/19/2022). *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 02/19/2022); 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 02/19/2022); https://news.yahoo.com/surgeon-general-vivek-murthy-says-205530053.html (quoting the Surgeon General referring to vaccine mandates as "reasonable") (last visited 02/19/2022).

regarding or reflecting the public discussion, discourse, and debate regarding the mandating or potential mandating of the Moderna Vaccine. PHMPT certifies that the information in this request is true and correct to the best of its knowledge and belief.

II. FEE WAIVER REQUEST

PHMPT is a nonprofit and asks that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" Specifically, disclosure of the requested information will immediately address the ongoing public debate about the safety and efficacy of the Moderna Vaccine and the clinical trials underlying the FDA's approval of same. The information PHMPT requests will not contribute to any commercial activities.

Note that in the event only a portion or 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 or can be deidentified. We further request that you describe any redacted, 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. PHMPT reserves all rights to appeal the withholding or deletion of any information.

A determination regarding expedited processing should be made within ten (10) days. 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 PHMPT may immediately file an administrative appeal or an action.

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

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Colin Farnsworth, Esq.