

FOIA Request Confirmation

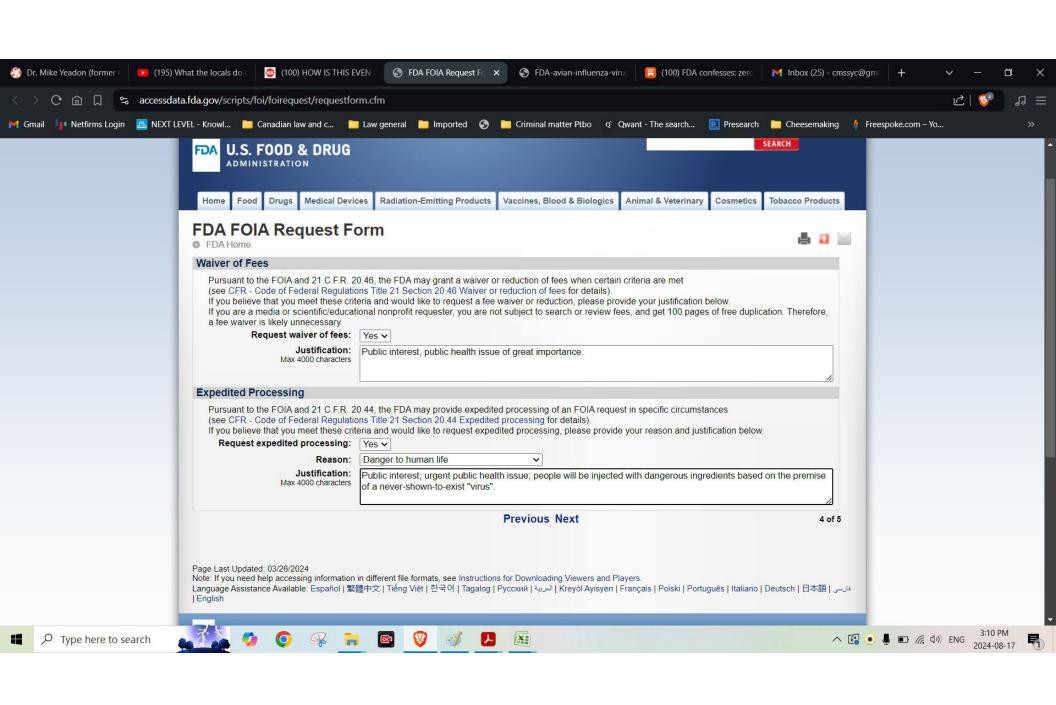
Confirmation Number: FDA24106238

Requester:

General								
Description of Requester: Educational institution or noncommercial scientific institution operated primarily for scholarly or scientific research								
Max Amount Willing to Pay: \$40								
Organization								
Organization Name: Fluoride Free Peel								
Primary Phone:	Other Phone:		Email:	cmssyc@gmail.com				
Mailing Address Billing Address								
Address 1:		Address 1:						
Address 2:		Address 2:						
City:		City:						
Province CA:		Province:						
Postal Code CA:		Postal Code:						
Country:		Country:						
Details								
Requester Name: Christine: House of Massey								
Requester File #:	Request Letter:							
Requested Date From:	01/01/1958	Requested Date To: 08/17/2024						
Subject of Request:	All studies in the possession/custody/control of the FDA, authored by anyone, anywhere: 1 that scientifically prove/provide evidence of the existence of any alleged "monkeypox virus" (showing that the alleged particles exist, invade and replicate in "host" cells and cause the illness/symptoms that they are alleged to cause). Note:							
Waiver of Fees								
Justification: Public interest, public health issue of great importance.								
Expedited Processing								
Reason: Danger to human life								
Justification: Public interest; urgent public health issue; people will be injected with dangerous ingredients based on the premise of a never-shown-to-exist "virus".								

Print Create Another Request Close

Within 10 business days of the submission of your online request, you will receive by electronic mail an FOIA Control Number. If you need to communicate with FDA regarding your request, please refer to this Control Number. Requests received after 4:00 P.M. E.S.T. will be considered to have been received on the following business day.





FDA Receipt of FOI Request Control # 2024-7353

FDA_FOI@fda.gov <FDA_FOI@fda.gov>

Sun, Aug 18, 2024 at 11:37 AM

To: cmssyc@gmail.com Cc: FDAFOIA@fda.hhs.gov

Control number: 2024-7353

Please find the attached acknowledgement regarding your FOIA request.

Note: Do NOT reply directly to this E-mail





August 19, 2024

FLUORIDE FREE PEEL CHRISTINE: HOUSE OF MASSEY In Reply refer to FOIA Control #: 2024-7353

Requester reference:

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

All studies in the possession/custody/control of the FDA, authored by anyone, anywhere: 1. - that scientifically prove/provide evidence of the existence of any alleged "monkeypox virus" (showing that the alleged particles exist, invade and replicate in "host" cells and cause the illness/symptoms that they are alleged to cause). Note: Scientific proof/evidence is not opinions, speculation, declarations, review papers or descriptive studies. Scientific evidence requires use of the scientific method to test falsifiable hypotheses through valid, rigorous, repeatable controlled experiments. 2. - that describe the purification of particles that are alleged to be "monkeypox virus" directly from bodily fluid/tissue/excrement of so-called "hosts" (without adding any sources of genetic material or proteins), with purification confirmed via EM imaging (the images must be available as well). Purify = separate from everything else in the clinical sample. I am aware that according to "virus" dogma a "virus" requires host cells in order to replicate. I am not seeking records describing the replication of a "virus" without host cells or that describe a suspected "virus "floating in a vacuum or a strict fulfillment of Koch's Postulates. I am simply seeking records that describe purification (separation from everything else in the "host" sample). I am not seeking private patient records. 3. - wherein the purported "genome" of any alleged "monkeypox virus" was found intact in the bodily fluid/tissue/excrement of a "host" (as opposed to fabricated in silico, aka a computer model). 4. - that scientifically demonstrate contagion of the illness / symptoms that are allegedly caused by purported "monkeypox viruses". If any records match the above description and are publicly available, please provide enough information about each one so that I may identify and access it with certainty (i.e. title, author(s), date, journal, URL, DOI). Send via email.

In processing your FOIA request, FDA will apply, as appropriate, the FOIA exemptions in 5 USC 552(b) and the foreseeable harm standard in 5 USC 552(a)(8)(i). We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm. PLEASE NOTE: HOURLY RATES FOR SEARCH AND REVIEW INCREASED FOR ALL REQUESTS RECEIVED ON OR AFTER JUNE 1. 2023.

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

If you have any questions about your request, please call Sarah B. Kotler, Director, Division Of Freedom Of Information, at (301) 796-8976 or write to us at:
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville. MD 20857

If you call or write, use the FOIA control number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

Office of Government Information Services National Archives and Administration 8601 Adelphi Road – OGIS and/or

FDA FOIA Public Liaison Office of the Executive Secretariat US Food and Drug Administration College Park, MD 20740-6001 Telephone:202-741-5770 Toll-Free: 1-877-684-6448

Email:ogis@nara.gov Fax: 202-741-5769 5630 Fishers Lane, Room 1050 Rockville, MD 20857 Email: FDAFOIA@fda.hhs.gov

Sincerely,

SARAH KOTLER Director



FDA FOIA 2024-7353

Kotler, Sarah <Sarah.Kotler@fda.hhs.gov>
To: "cmssyc@gmail.com" <cmssyc@gmail.com>

Tue, Aug 20, 2024 at 12:20 PM

Dear Requester,

I am writing in response to your request for:

All studies in the possession/custody/control of the FDA, authored by anyone, anywhere: 1. - that scientifically prove/provide evidence of the existence of any alleged "monkeypox virus" (showing that the alleged particles exist, invade and replicate in "host" cells and cause the illness/symptoms that they are alleged to cause). Note: Scientific proof/evidence is not opinions, speculation, declarations, review papers or descriptive studies. Scientific evidence requires use of the scientific method to test falsifiable hypotheses through valid, rigorous, repeatable controlled experiments. 2. - that describe the purification of particles that are alleged to be "monkeypox virus" directly from bodily fluid/tissue/excrement of socalled "hosts" (without adding any sources of genetic material or proteins), with purification confirmed via EM imaging (the images must be available as well). Purify = separate from everything else in the clinical sample. I am aware that according to "virus" dogma a "virus" requires host cells in order to replicate. I am not seeking records describing the replication of a "virus" without host cells or that describe a suspected "virus "floating in a vacuum or a strict fulfillment of Koch's Postulates. I am simply seeking records that describe purification (separation from everything else in the "host" sample). I am not seeking private patient records. 3. - wherein the purported "genome" of any alleged "monkeypox virus" was found intact in the bodily fluid/tissue/excrement of a "host" (as opposed to fabricated in silico, aka a computer model). 4. - that scientifically demonstrate contagion of the illness / symptoms that are allegedly caused by purported "monkeypox viruses". If any records match the above description and are publicly available, please provide enough information about each one so that I may identify and access it with certainty (i.e. title, author(s), date, journal, URL, DOI). Send via email.

The FDA does not regulate or treat viruses. The FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. Therefore, we have no responsive records. If you are interested, we have already made information public regarding the milk supply (Updates on Highly Pathogenic Avian Influenza (HPAI) | FDA) and the process for approval of Avian Influenza test kits. (Influenza Diagnostic Tests | FDA).

In accordance with 45 CFR § 5.61 and 21 CFR § 20.41(b)(5), you have the right to appeal this determination. Your appeal should clearly identify the agency determination that is being appealed. It would be helpful if you provide specific reasons explaining why you believe the agency's adverse determination should be reconsidered. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed within 90 days from the date of this response, to: Director, Office of the Executive Secretariat, U.S. Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, or emailed within 90 days from the date of this response to

FDAFOIA@fda.hhs.gov. Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal." Items arriving or delivered after 5 p.m. Eastern Time will be deemed received on the next workday.

If you would like to discuss our response <u>before</u> filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact me at 301-796-8976 or <u>Sarah.Kotler@fda.hhs.gov</u>.

Please contact me if you have questions about your request. You may also contact the FDA FOIA Public Liaison for assistance at: Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road–OGIS, College Park, MD 20740-6001; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769; e-mail at ogis@nara.gov.

Sincerely,

Sarah B. Kotler, J.D.

Director, Division of Freedom of Information

US FDA

301-796-8976



FDA FOIA 2024-7353

Christine, an unincorporated woman <cmssyc@gmail.com> To: "Kotler, Sarah" <Sarah.Kotler@fda.hhs.gov>

Tue, Aug 20, 2024 at 4:27 PM

Thank you Sarah,

Would you please put the response in a letter that is signed and without the irrelevant references to "avian influenza".

Regards, Christine [Quoted text hidden]



August 21, 2024

By email to: cmssyc@gmail.com

Dear Requester,

I am writing in response to your request for:

All studies in the possession/custody/control of the FDA, authored by anyone, anywhere: 1. - that scientifically prove/provide evidence of the existence of any alleged "monkeypox virus" (showing that the alleged particles exist, invade and replicate in "host" cells and cause the illness/symptoms that they are alleged to cause). Note: Scientific proof/evidence is not opinions, speculation, declarations, review papers or descriptive studies. Scientific evidence requires use of the scientific method to test falsifiable hypotheses through valid, rigorous, repeatable controlled experiments. 2. - that describe the purification of particles that are alleged to be "monkeypox virus" directly from bodily fluid/tissue/excrement of socalled "hosts" (without adding any sources of genetic material or proteins), with purification confirmed via EM imaging (the images must be available as well). Purify = separate from everything else in the clinical sample. I am aware that according to "virus" dogma a "virus" requires host cells in order to replicate. I am not seeking records describing the replication of a "virus" without host cells or that describe a suspected "virus "floating in a vacuum or a strict fulfillment of Koch's Postulates. I am simply seeking records that describe purification (separation from everything else in the "host" sample). I am not seeking private patient records. 3. - wherein the purported "genome" of any alleged "monkeypox virus" was found intact in the bodily fluid/tissue/excrement of a "host" (as opposed to fabricated in silico, aka a computer model). 4. - that scientifically demonstrate contagion of the illness / symptoms that are allegedly caused by purported "monkeypox viruses". If any records match the above description and are publicly available, please provide enough information about each one so that I may identify and access it with certainty (i.e. title, author(s), date, journal, URL, DOI). Send via email.

The FDA does not regulate or treat viruses. The FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. Therefore, we have no responsive records. For general information on FDA's involvement with mpox, please see: FDA Mpox Response | FDA.

In accordance with 45 CFR § 5.61 and 21 CFR § 20.41(b)(5), you have the right to appeal this determination. Your appeal should clearly identify the agency determination that is being appealed. It would be helpful if you provide specific reasons explaining why you believe the agency's adverse determination should be reconsidered. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed within 90 days from the date of this response, to: Director, Office of the Executive Secretariat, U.S. Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, or emailed within

90 days from the date of this response to FDAFOIA@fda.hhs.gov. Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal." Items arriving or delivered after 5 p.m. Eastern Time will be deemed received on the next workday.

If you would like to discuss our response <u>before</u> filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact me at 301-796-8976 or <u>Sarah.Kotler@fda.hhs.gov</u>.

Please contact me if you have questions about your request. You may also contact the FDA FOIA Public Liaison for assistance at: Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road—OGIS, College Park, MD 20740-6001; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769; e-mail at ogis@nara.gov.

~ :				1
SI	n	ce	re	١٧,

Sarah Kotler



FDA FOIA 2024-7353

Christine, an unincorporated woman <mssyc@gmail.com>
To: "Kotler, Sarah" <Sarah.Kotler@fda.hhs.gov>

Wed, Aug 21, 2024 at 9:04 AM

Thank you Sarah.

I published your response, and someone left the comment below. Will you or someone at the FDA issue a response? Many people would also like an answer, including myself.

Also, I would like to point out that "just doing my job" is not a lawful excuse for "scientists" and others who make fraudulent claims about products and "viruses".

"Call me crazy, but I have a question for Sarah.

She says: "The FDA does not regulate or treat viruses. The FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. Therefore, we have no responsive records." (emphasis added)"

As logic would follow, then we have to ask how the hell do you verify that there is a threat that requires the "safe drugs and biological products" that you supposedly investigate (which apparently you aren't very good at given your history of recalls for product(s) that killed lots of people)? Put another way, in order to scrutinize the safety and efficacy of a drug/biological, you'd have to comb through the studies that provide that evidence. Yes? Then you'd have them on record. Or do you just take the company's word for it? You at least ask for the drug trial data, yes? Make a copy for the file room?

What about the threat that endangers all of us so? How do you verify the cause of the alleged threat, or that it is a real threat, to make sure the drug/biological is even necessary? Shouldn't that be part of the process?

What if I come to you, the FDA, and say "looky here, My name is Dr. Mengele and I work for AstraPfizerca Glaxoderna. I have developed a special potion that I tested on some people. I'll be happy to show you the results. What's it for, you say? Strange question but OK. Well, it cures a nasty little skin disease we decided to label Corn Pox- caused by excess unicorn farts that have been wafting through the backyards and community playgrounds of our peoples. You can't see or even SMELL the farts. In fact, you can't even see the unicorns, but just take my word for it. It is happening- we published some stuff in a journal that has the word science on it (and it's way above your head). Now please approve my potion. That's what you do. You don't check to find evidence of the unicorns, you leave that to us. BTW, there's a lucrative job for you in my offices after you revolve out the FDA door."

Dear Sarah, is this how it works? Is this how you keep us all safe?"

Regards,



FDA FOIA 2024-7353

Christine, an unincorporated woman <cmssyc@gmail.com>
To: "Kotler, Sarah" <Sarah.Kotler@fda.hhs.gov>

Wed, Aug 21, 2024 at 9:22 AM

p.s. A colleague has further noted the following and we ask for a response to this as well:

"On the FDA website under "Protecting against fraudulent products and false information" on the FDA MPox response page, they say:

"The FDA monitors for fraudulent products and false product claims related to CBRN (chemical, biological, radioactive, nuclear) and emerging infectious disease threats and takes appropriate action to protect consumers."

Yet according to her response to you, this would be an impossibility (or an outright lie). You can't monitor for a fraudulent product if you claim it isn't your job to monitor for a fraudulent disease or a fraudulent cause of a fraudulent disease. How would you even know if the product passes the first step.....NECESSARY AT ALL...?

..

- 1) Your (Sarah) response is a tacit admission that you are either:
- A) Not interested in scientific inquiry regarding claims of disease and their causes (you take anyone at their word and go off hearsay and conjecture).
- B) Do not have the scientific personnel to perform such an inquiry.
- C) Defer to someone or some other institution to declare certain disease/cause threats and operate without your own investigation. Subsequently, that means you approve drugs/biologics for which you can't possibly know anything about because you don't investigate the actual disease and cause. "You have no records".
- D) None of the above, we just don't have a copy machine or a file cabinet. Times are tough.

If it is C, then we have a follow up question. Who** are you deferring to that is making the claim of a public "biological" threat for which your agency does not do its own investigation? Can you list them for us? What is the chain of command since you are claiming no responsibility and approving drugs for 'diseases' that you have no scientific understanding of?

- 2) Do you check the veracity of any such claims at all? If so, how?"
- **Special note: Major health institutions including the CDC and NIAID have also admitted to having **no records to show the existence of the alleged "monkeypox virus"** (or "SARS-COV-2", or **any other alleged "virus"** that they've been asked about). So it appears your agency is sitting on a medical merry-go-round that purports to be protecting the public but without any of the necessary scientific evidence (and records of it) to substantiate your claimed function as a public service. This could become a serious problem for you.

[Quoted text hidden]