



Göran Marby  
President and Chief Executive Officer  
Internet Corporation for Assigned Names and Numbers (ICANN)  
12025 Waterfront Dr Ste 300  
Los Angeles, CA 90094

Dear Mr. Marby:

This letter is in reply to your correspondence to the U.S. Food and Drug Administration (FDA) Commissioner Robert Califf dated June 14, 2022, offering clarifications to statements reportedly made about ICANN during a presentation by Special Agent ("SA") Dan Burke, a Division Chief with oversight of Cyber Operations including the Cybercrime Investigations Unit within FDA's Office of Criminal Investigations (OCI).

FDA is responsible for protecting public health by, among other things, ensuring the safety, efficacy, and security of medical products, including drugs and medical devices. Almost all of these regulated products are sold online. As FDA's criminal law enforcement arm, the OCI, protects the American public by conducting criminal investigations of illegal activities involving FDA-regulated products, arresting those responsible, and bringing them before the U.S. Department of Justice for prosecution. The special agents assigned to OCI's Cybercrime Investigations Unit are on the frontlines of cybercrime involving FDA-regulated products. SA Burke has been a long-term participant in the U.S. Government's DNS interagency working group on behalf of FDA.

You cite a concern raised in the presentation that "*A requester must have a subpoena to access non-public registration data*" and proceed to explain that "*It is not necessary to obtain a subpoena to gain access to non-public domain name registration data.*" Unfortunately, as SA Burke noted, this is not the actual experience of FDA-OCI special agents who, when requesting non-public domain name registration data from any one of the over 2,400 ICANN-accredited registrars operating globally<sup>1</sup>, are often asked to submit a subpoena, court order (sometimes within the jurisdiction of the registrar), or Mutual Legal Assistance Treaty (MLAT) to obtain such information. However, since personal contact information within WHOIS records became unavailable to U.S. investigators under ICANN's implementation of the European General Data Protection Regulation (GDPR) in 2018, the issue regarding WHOIS access for public health and law enforcement agencies is still unresolved some four years later. Requests for legal process/orders from registrars understandably cause delay in FDA-OCI's investigations. We appreciate the information that our FDA-OCI special agents can submit a complaint to ICANN regarding access to registration data and anticipate using this process to ensure that FDA-OCI can quickly obtain non-public domain name registration data from registrars who are not abiding by ICANN's current policy.

You noted in your letter another concern raised by SA Burke in the presentation: "*ICANN ignores complaints from government agencies, particularly about malicious activity related to COVID.*" You note in your letter that ICANN proactively worked to "look at registrations related to the COVID-19 pandemic to

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<sup>1</sup> <https://www.icann.org/en/accredited-registrars>

find evidence of any activity related to malware or phishing." DNS security threats such as malware and phishing, however, were not what SA Burke was referring to in his presentation. Given the agency's public health mission, FDA has been working during the pandemic to protect Americans from unproven or fraudulent medical products claiming to treat, cure, prevent, mitigate, or diagnose COVID-19.<sup>2</sup> As part of this effort, FDA has sent hundreds of abuse complaints to domain name registrars and internet marketplaces. And as you are aware, ICANN's 2013 Registrar Accreditation Agreement (RAA) requires registrars to maintain an abuse point of contact to receive "reports of abuse involving Registered Names sponsored by Registrar, including reports of Illegal Activity," and to "take reasonable and prompt steps to investigate and respond appropriately" to any reports of abuse.<sup>3</sup> Given your stated concerns regarding COVID-19-related malware and phishing activity, we trust that you are equally concerned about registrars who may not be following the RAA's requirements to "investigate" and "respond appropriately" following receipt of notifications of abuse, particularly complaints reporting activity involving COVID-19-related fraud or activity exacerbating the current opioid addiction crisis<sup>4</sup> – especially in light of ICANN's singular ability to enforce the terms of RAAs.

Finally, SA Burke was not referring to ICANN's leadership's salaries, as suggested in your letter. Instead, SA Burke was referring more generally to the substantial source of funding ICANN receives from domain name registries and registrars.<sup>5</sup>

Thank you for your comments and clarifications. FDA-OCI will continue to participate in the U.S. Government's DNS interagency working group. We hope this letter provides helpful information regarding FDA-OCI's perspective on these issues, as well as FDA's overarching mission to protect public health.

Sincerely,



Catherine A. Hermsen  
Assistant Commissioner for Criminal Investigations

cc: The Honorable Alan Davidson  
Assistant Secretary of Commerce  
Administrator, National Telecommunications and Information Administration  
U.S. Department of Commerce  
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Washington, D. C. 20230

<sup>2</sup> See <https://www.fda.gov/news-events/fda-voices/fda-protects-patients-and-consumers-fraud-during-covid-19>, describing FDA's Operation Quack Hack.

<sup>3</sup> 2013 RAA, Section 3.18.1-2

<sup>4</sup> [Drug Overdose Deaths in the U.S. Top 100,000 Annually \(cdc.gov\)](https://www.cdc.gov/drugoverdose/deaths-top-100000-annually)

<sup>5</sup> <https://www.icann.org/en/system/files/files/fy21-funding-source-30jun21-en.pdf>;