## **EXHIBIT P**

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Appeal file: 21-0020AA

FOIA file: 2019-4472, 2019-4465, 2019-4457, 2019-4455, 2019-4428

April 29, 2021

Sending via Email: stephen.stich@YLSClinics.org

Dear requester,

This is in response to your April 29, 2021 letter to attempt to appeal FDA's failure to respond to your FOIA requests. HHS's regulation at 45 CFR 5.61 provides a right to appeal only after an adverse determination by FDA. As no adverse determination has yet been made, there is no action for this office to consider under appeal. This letter will close your appeal and allow the necessary, remaining processes to take place in response to your initial request.

Once the FDA issues their final response, you will receive appeal rights for any possible denials or other appealable issues.

If you would like to check on the status of your request, you may 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: <a href="mailto:FDAFOIA@fda.hhs.gov">FDAFOIA@fda.hhs.gov</a>.

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.

You have the right to judicial review of this action in a United States District Court in accordance with 5 USC § 552(a)(4)(B).

Sincerely yours,

Katherine Digitally signed by Katherine N. Uhl -S Date: 2021.04.29 09:03:00 -04'00'

Katherine Uhl Denials and Appeals Officer FDA FOIA

U.S. Food and Drug Administration 5630 Fishers Lane, Room 1035 Rockville, MD 20857 www.fda.gov