U.S. FOOD & DRUG ADMINISTRATION

April 22, 2020

Request Number: 2020-2837

Jeff Bourland
Shadyside Partners, LLC
605 Liberty Ave.
Pittsburgh, IL 60610

Subject of Request: Cytodyn, Inc Leronlimab emergency investigational new drug files granted for treatment of patients with covid-19

Dear requester:

The Food and Drug Administration (FDA) has completed processing your request for records under the Freedom of Information Act (FOIA).

We are denying your entire request. Specifically, we are denying records from an unapproved product application.

The following exemption of FOIA, 5 U.S.C. 552, are the authority for denying you access to the non-disclosable material: Exemption (4) Trade secret and confidential commercial information, Exemption (b)5 Certain interagency and intra-agency communications, and Exemption(6) Information about individuals in personnel, medical and similar files when disclosure would constitute a clearly unwarranted invasion of privacy. We have included citations to the FOIA and FDA's regulations for your information.

Section 5.31(d), (e), and (f) of the implementing regulations of the Department of Health and Human Services (DHHS) are applicable to this denial. The regulations are contained in the Code of Federal Regulations (CFR), Title 45.

The following sections of the implementing regulations of FDA and reasons applicable to this denial contained in the Code of Federal Regulations (CFR), Title 21 are

- 20.61(b)(c), 312.130(b), and 314.430(d)(1) Trade secret and confidential commercial information in general, and information, not previously publicly disclosed, in a pending New Drug Application (NDA).
- Section 20.62 Intra-agency memoranda consisting of opinions, recommendations, and policy discussions within the deliberative process of FDA, from which factual information is not reasonably segregable.
- 20.63 Personnel, medical and similar files

FDA's Regulations at CFR Part 20 are available at:
http:www.access.gpo.gov/nara/cfr/waisidx_04/21cfr20_04.html

You have the right to appeal this determination. 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: Agency Chief FOIA Officer, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Public Affairs, Room 729H, 200 Independence Avenue, S.W., Washington, DC 20201; e-mail FOIARequest@PSC.hhs.gov. Please clearly mark both the envelope and your letter or e-mail " **FDA** Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact **Katherine Uhl 301-796-8975**. 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.

If you have any questions, please contact **Katherine Uhl at 301-796-8975.**

Sincerely yours,

Sarah B. Kotler -S

Digitally signed by Sarah B. Kotler -S
Date: 2020.04.22 08:12:25 -04'00'

Sarah Kotler
Director
Division of Freedom of Information