



November 28, 2023  
FOIA request #: 2023-162

Sarah Price Hancock  
8460 Roach Drive  
La Mesa, CA 91942

Dear Sarah Price Hancock:

This letter is in response to your Freedom of Information Act (FOIA) request (copy attached) dated 01/05/2023, and received by the Food and Drug Administration (FDA) on 01/05/2023. In your request, you sought a copy of the following records:

“Somatics’ Thymatron System IV premarket approval applications (PMA) and notices of completed product development protocols (PDP) submitted to the FDA before March 27, 2019 for a use on people diagnosed with bipolar and schizoaffective disorder. I also request dosing consensus standards for people diagnosed with bipolar and schizoaffective disorder.”

The Center for Devices and Radiological Health (CDRH) conducted a reasonable search of:

510(k) Premarket Notification database, Image2000+, Premarket Approval (PMA) database, Establishment Registration & Device Listing database

Unfortunately, after a reasonable search, we were unable to locate records responsive to your request. This completes the response from CDRH.

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: Director, Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: [FDAFOIA@fda.hhs.gov](mailto:FDAFOIA@fda.hhs.gov).

Please clearly mark both the envelope and your letter or email “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 Julia Drake who processed this request at (240) 402-6495 or by email at [Julia.Drake@fda.hhs.gov](mailto:Julia.Drake@fda.hhs.gov). 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](mailto: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: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road–OGIS, College Park, MD

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20903  
[www.fda.gov](http://www.fda.gov)



20740-6001; Telephone: 202-741-5770; Toll-Free: 1-877-684-6448; E-mail: [ogis@nara.gov](mailto:ogis@nara.gov) ; Fax: 202-741-5769.

X The following charges may be included in a monthly invoice:

**Reproduction: \$0.00 Search: \$129.00 Review: \$0.00 Other: \_\_\_\_\_ Total: \$ 129.00**

Sincerely,

Candace Boston Davis  
Director  
Division of Information Disclosure  
Office of Communication and Education  
Center for Devices and Radiological Health  
Food and Drug Administration