

# **EXHIBIT B**



April 11, 2023

MCDERMOTT WILL & EMERY  
PAUL W. HUGHES  
500 North Capitol St NW  
McDermott Will & Emery  
Washington DC 20001 US

In Reply refer to  
FOIA Control #:  
2023-2856

Requester reference:

Dear Requester:

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

Any discipline reviews (including the Clinical Review and Clinical Pharmacology Review) prepared in the course of FDA's evaluation of sNDA 205677/S-005.

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>.

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 Pamela A. Prue, Information Technician, at (301) 796-8984 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  
College Park, MD 20740-6001  
Telephone: 202-741-5770  
Toll-Free: 1-877-684-6448  
Email: [ogis@nara.gov](mailto:ogis@nara.gov)  
Fax: 202-741-5769

and/or

FDA FOIA Public Liaison  
Office of the Executive Secretariat  
US Food and Drug Administration  
5630 Fishers Lane, Room 1050  
Rockville, MD 20857  
Email: [FDAFOIA@fda.hhs.gov](mailto:FDAFOIA@fda.hhs.gov)

Sincerely,

SARAH KOTLER  
Director