



July 23, 2019

Siri & Glimstad LLP  
200 Park Avenue  
Seventeenth Floor  
New York, NY 10166

In reply, refer to file: F18-6943

Dear Mr. Siri,

This is in reply to your Freedom of Information Act request dated August 22, 2018, in which you requested "A copy of the report for each clinical trial relied upon by the FDA when approving Ipol in 1990." Your request was received in the Center for Biologics Evaluation and Research on August 24, 2018.

A search of the IPOL product license application file located the enclosed documents that are responsive to your request. Please note that we have provided you with the best available copies of the records.

We have withheld portions of pages under Exemption (b)(4), 5 U.S.C. § 522(b)(4). That exemption permits the withholding of trade secrets and commercial or financial information that was obtained from a person outside the government and that is privileged or confidential. The withholding of such information is permitted if disclosure is likely to cause substantial competitive harm to the person who submitted the information.

In addition, we have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

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:

Deputy 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  
Email: FOIARequest@PSC.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:

Beth Brockner-Ryan, Branch Chief  
Center for Biologics Evaluation and Research (CBER)  
Access Litigation and Freedom of Information Branch  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Building 71, Room 1114  
Silver Spring, MD 20993-0002  
Email: [beth.brocknerryan@fda.hhs.gov](mailto:beth.brocknerryan@fda.hhs.gov)  
Main Line 240-402-7800  
FOI Line 240-402-8008

You also have the right to contact:

FDA FOIA Public Liaison  
Office of the Executive Secretariat  
5630 Fishers Lane  
Room-1050  
Rockville, MD 20857  
Email: [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 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

The following may be included in a monthly invoice:

Reproduction	1 CD @ \$1.00	\$1.00
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<b>TOTAL</b>		<b>\$1.00</b>
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The above charges may not reflect final charges for this request. Please DO NOT send any payment until you receive an invoice from the Agency's Freedom of Information Staff (HFI-35).

If you have any questions or if we can be of further assistance, please let us know by referencing the above file number. You can contact Mechelle Bray by phone at 240-402-8024 or by e-mail at [Mechelle.Bray@fda.hhs.gov](mailto:Mechelle.Bray@fda.hhs.gov).

Sincerely,

Beth Brockner Ryan  
Chief, Access Litigation and Freedom of Information Branch