



October 7, 2020

Elizabeth A. Brehm, Esq.
C/O Siri & Glimstad LLP
Informed Consent Action Network
200 Park Avenue, 17th Floor,
New York, NY 10166

In reply refer to file: F20-6075,

Dear Ms. Brehm,

This letter is in partial response to your Freedom of Information Act request dated August 19, 2020, in which you requested:

“The following data and information in the biological product file for Gardasil (refers to the product referenced herein, <https://www.fda.gov/media/74350/download>, licensed in 2006):

- (1) All safety and efficacy data and information;
- (2) All protocols for a test or study;
- (3) All adverse reaction reports, product experience reports, consumer complaints, and other similar data and information;
- (4) A list of all active ingredients and any inactive ingredients previously disclosed to the public;
- (5) An assay method or other analytical method; and
- (6) All correspondence and written summaries of oral discussions relating to the biological product file.”

Your request was received in the Center for Biologics Evaluation and Research on August 20, 2020.

Enclosed are previously released Gardasil documents that are responsive to your request. The remainder of your request will be processed as soon as practicable.

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.

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.

Information about how to appeal these withholdings will be provided with your final response.

The following may be included in a monthly invoice:

Reproduction	6 CDs @ \$1.00/CD	\$6.00
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TOTAL		\$6.00

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).

As we continue to process the remaining portion(s) of your request, if we can be of further assistance please let us know by referencing the above file number. You can contact Ashlee Eswara by phone at 240-402-8008 or by e-mail at Ashlee.Eswara@fda.hhs.gov. We appreciate your patience and understanding.

Sincerely,

Ashlee L. Eswara, Microbiologist
Access Litigation and Freedom of Information Branch
Center for Biologics Evaluation and Research
Food and Drug Administration