

Appeal Number: 96-A-084

AUG 20 1996

Mr. Roger C. Thies
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005

Dear Mr. Thies:

This is in response to your July 12 letter in which you appeal the decision of the Food and Drug Administration (FDA) to deny you access to information in the Agency's possession. I have been designated to act on behalf of the Assistant Secretary for Public Affairs in responding to your appeal. I have completed my review of your appeal and the records at issue.

Your firm submitted a request, dated May 28, 1996, under the Freedom of Information Act (FOIA), for copies of all publicly available information contained in Biogen, Inc.'s Product License Application (PLA) and Establishment License Application (ELA) for Avonex. The PLA and ELA are components of the biological product file for Avonex (the Avonex file). By letter dated, June 13, 1996, FDA denied the request for information in the Avonex file that constitutes trade secret or confidential commercial information. You appeal this denial claiming that none of the information that FDA withheld is trade secret or confidential commercial information. You also write that if there is trade secret or confidential commercial information in the Avonex file, FDA should disclose any publicly-releasable records in the Avonex file.

You contend in your appeal letter that none of the information contained in the Avonex PLA and ELA falls within Exemption 4 of the FOIA. We disagree. FDA Regulation, 21 C.F.R. 601.51(f) states, in pertinent part:

The following data and information in a biological product file are not available for public disclosure unless ... they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter:
(1) Manufacturing methods or processes, including quality control procedures.

The Avonex file contains such information.

You specifically argue that any safety and effectiveness data in the Avonex file is not confidential commercial information. As FDA indicated in its denial letter, extraordinary circumstances

exist, within the meaning of 21 C.F.R. 601.51(e), that preclude FDA from publicly disclosing the Avonex pivotal clinical safety and effectiveness data. According to FDA, extraordinary circumstances exist for the following reasons. First, Dr. Rentschler Biotechnologie (Rentschler), is an affiliate of your client, Berlex. Berlex sought a temporary restraining order to prevent FDA from licensing Avonex and is the plaintiff in currently pending litigation in which it seeks to compel FDA to rescind the May 1996 licensing of Avonex. Berlex v. FDA, et al. Rentschler was involved with Biogen in a joint venture that sought to develop an interferon-beta product similar to Avonex for licensure. Biogen owns the clinical data from this joint venture and used this data to support its application for Avonex. Rentschler apparently owns the master cell bank for the original interferon-beta product used to generate the clinical trial data that Biogen owns and submitted to FDA in support of its Avonex application. FDA has determined that Avonex is comparable to the interferon-beta product that was studied in these clinical trials. Therefore, after Biogen's orphan exclusivity for Avonex expires, if Rentschler or its affiliate has access to this pivotal clinical data, Rentschler or an affiliate could obtain FDA licensure of Rentschler's own interferon-beta product, based on the same data that Biogen used to obtain FDA licensure of Avonex.

Officials from FDA advise that these unique facts comprise an extraordinary circumstance within the meaning of 21 C.F.R. 601.51(e). Disclosure of this data would destroy a competitive advantage that Biogen would otherwise enjoy since it owns the data in question and Rentschler and its affiliates have no such ownership rights. 39 Fed. Reg. 44602, 44632 (December 24, 1974). Thus, the clinical data in the Avonex file retains its confidential commercial nature.

Secondly, Biogen has demonstrated to FDA, through letters dated March 1, 1996, and May 7, 1996, that specific facts exist that suggest that Rentschler, Berlex, or their affiliates could obtain a competitive advantage over Biogen by pursuing approval, based upon the clinical data in the Avonex file, of their own interferon-beta product in specific foreign markets. 39 Fed. Reg. 44602, 44632 (December 24, 1974). This is an extraordinary circumstance which necessarily indicates that this data retains its confidential commercial value.

Similarly, other safety and effectiveness data, such as certain pre-clinical data, in the Avonex file remain confidential commercial information for the reasons described above.

You request that FDA segregate the trade secret and confidential commercial information in the Avonex file and that FDA "immediately" release any publicly available information from

this file, which consists of approximately 65,000 pages of records. As you know, FDA has already publicly disclosed over 400 pages of records from the Avonex file. In response to your request, FDA will review the Avonex file to ensure that all publicly disclosable information that you have requested has been, and is released to you. Given the size of the Avonex file and the number of records contained therein, FDA requests that you pay an estimated fee in advance pursuant to 21 C.F.R. 20.42(d)(2). Please contact Donald Fowler, Chief, Access Litigation and Freedom of Information Branch, Center for Biologics Evaluation and Research at 301-827-2000 in order to promptly receive an estimate of the required fee.

I have determined to continue to withhold the data and information in the Avonex file that constitutes trade secret or confidential commercial information within the meaning of Exemption 4 of the FOIA. 5 U.S.C. 552(b)(4). Such information includes manufacturing methods or processes, production data, comparability data, and safety and effectiveness data. 21 C.F.R. 20.61; 601.51. The Food, Drug, and Cosmetic Act, 21 U.S.C. 331(j) and the Trade Secrets Act, 18 U.S.C. 1905, prohibit FDA from publicly releasing such information. In addition, to the extent that, in the Avonex file, there is information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such information is exempt from disclosure. 5 U.S.C. 552(b)(6).

This letter constitutes the final decision of the Department in this matter. If you wish, you may seek judicial review in the district court of the United States in the district in which you reside, have your principal place of business, or in which the agency records are located, or in the District of Columbia.

Sincerely yours,



Victor F. Zonana
Deputy Assistant Secretary
for Public Affairs