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April 19, 2007

VIA FACSIMILE (301) 443-1726 AND REGULAR MAIL

Food and Drug Administration
Office of Management Programs
Division of Freedom of Information (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Re: Freedom of Information Act Request (FOIA)

Dear Sir or Madam:

Pursuant to the Freedom of Information Act 5 U.S.C. § 552, as amended, and in accordance with the procedures set forth in 21 CFR Part 20 and the procedures you have set forth at <http://www.fda.gov/opacom/backgrounders/foiahand.html>, I am requesting that you provide copies of the below described documents and records as they pertain to the Novartis Pharmaceuticals Corporation's drug Zelnorm (tegaserod maleate).

My Name is: Tracy A. Finken, Esquire

My Address is: Anapol, Schwartz, Weiss, Cohan, Feldman & Smalley, P.C., 1710 Spruce Street, Philadelphia, PA 19103

My Telephone Number is: (215) 735-0773

Description of Documents and Records Sought:

- Documents concerning epidemiology of Zelnorm and its side effects
- Correspondence with Novartis Pharmaceuticals Corporation concerning approval of Zelnorm
- Documents concerning epidemiology that led FDA to request Novartis Pharmaceuticals Corporation cease marketing of Zelnorm
- Correspondence with Novartis Pharmaceuticals Corporation concerning cessation of marketing of Zelnorm
- Hearing Transcripts related to or that formed the basis of approval of and subsequent request to remove Zelnorm from the market

1900 Delancey Place
Philadelphia, PA 19103

1710 Spruce Street
Philadelphia, PA 19103

1040 Kings Hwy. North, Suite 304
Cherry Hill, NJ 08034

146 N. 6th Street
Reading, PA 19601

334 W. Front Street
Media, PA 19063

209 State Street
Harrisburg, PA 17101

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Haverford, PA 19041

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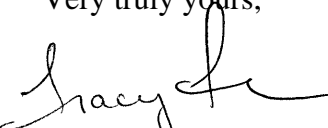
- Safety and effectiveness data submitted to the Food and Drug Administration (FDA) for Zelnorm
- Study protocols and adverse reaction reports concerning Zelnorm
- Documents related to the testing of Zelnorm
- Documents about the marketing of Zelnorm

Product Involved: Zelnorm (tegaserod maleate).

Fees: We are willing to pay fees up to \$250.00 and will pay by check, as requested.

If you have any questions or concerns, please feel free to contact me.

Very truly yours,



Tracy A. Finken

TAF/pm

cc: Michael Monheit, Esquire