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January 10, 2011

Food and Drug Administration  
Division of Freedom of Information (HFI-35)  
Office of Shared Services  
Office of Public Information and Library Services  
Attn: Ms. Thelma Ghahhari  
5600 Fishers Lane  
Rockville, MD 20857

RE: FREEDOM OF INFORMATION ACT REQUEST

Dear FDA Freedom of Information Group,

Please consider this a request under the Freedom of Information Act (FOIA).

We request copies of all documents and e-mails sent to and from Dr. Richard Pazdur, the Director of the Office of Oncology Drug Products, CDER, relating to Dendreon Corporation's prostate cancer immunotherapeutic agent sipuleucel-T (Provenge), which Dr. Pazdur would have sent and/or received during the period, October 1, 2006 through October 1, 2007, inclusive.

This request includes all documents and envelopes, whether it be via the US Post Office mail, e-mails, including internal e-mails summarizing telephone and/or other conversations, letters, minutes from meetings, faxes and memoranda pertaining to telephone conversations that were a result of anyone sending information to or receiving information from Dr. Richard Pazdur in regards to Provenge.

We request copies of all correspondence, whether electronic or otherwise, and all notes made by government and special government employees (consultants) regarding all views expressed to Dr. Pazdur, including, where available, the originating phone number in cases where the conversations were oral in nature, and/or notes identifying the caller and/or the location of the calls and all communications then made when those views were communicated to Dr. Pazdur. All phone logs or evidence of formal or informal discussions or communications, internal or external, should be included.

We request Dr. Pazdur's computer(s) be searched, as well as any portable hard drives, diskettes, CDs, memory sticks and other portable memory devices. In addition, we request that a thorough search be made of the FDA's e-mail server and its backup server, as well as any backup devices to these servers, including, but not limited to, Tape Backups, NAS Backups, SAN Backups, Flash Drives, CDs, or DVDs. We request network audit trail logs be checked for the time period specified, especially including the month of May 2007 when Dr. Pazdur declared he deleted the sought-after documents and e-mails.

Keyword searches to be used in the search for relevant documents should include the following words/phrases:

Andrew Von Eschenbach, Howard Scher, Maha Hussain, Salam Jafer Hussain, Thomas Fleming, Savio Lau-Ching Woo, Alison Martin, Steven Rosenberg, Howard Streicher, Paul Goldberg, Stephen Lieberman, Matthew

Herper, Gardiner Harris, Michael Milken, Vincent DeVita, James Mulé, Jesse Goodman, Celia Witten, Karen Midthun, Mary Foulkes, Eric Small, Christopher Logothetis, Donald Berry, Jay Moorin, Jonathan Simons, and Howard R. Soule. Prostate Cancer Foundation, PCF, Dendreon, including misspellings like Dendrion and sipuluecel-T. Provenge, Cougar, Cougar Biotechnology, Abiraterone, CB7630, Novacea, Asentar, ASCENT1, ProQuest Investments, “The Cancer Letter”, Schering-Plough, Memorial Sloan-Kettering, M.D. Anderson, the University of Michigan Comprehensive Cancer Center, and the University of Washington. Phrases such as “CBER Advisory Meeting on Provenge”, “GoodmanFDASipuleucel.doc”, “CBER Advisory Committee for Sipuleucel-T”, “Sipuleucel-T in prostate cancer”, Goodman.pdf”, “Letter re- recent advisory com. mtg”, “FDA Mtg Response 4.23.07.pdf”, “With your blessings – will circulate to authors this week.” and “Provenge\_draft.doc”.

We are willing to pay all costs associated with complying with this request.

Thank you for processing this request at your earliest convenience.

Sincerely,

\_\_\_\_\_/s/

Mike Kearney  
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