DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN - 2 2008

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

Thank you for the letter dated June 15, 2007, co-signed by Chairman Bart Stupak, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, to Secretary Michael O. Leavitt, Health and Human Services, requesting information and documents related to Erythropoiesis-Stimulating Agents (ESAs). Secretary Leavitt asked that the Food and Drug Administration (FDA or the Agency) respond on his behalf. On September 26, 2007, January 10, 2008, and April 17, 2008, we sent a partial response. This is a final response.

On May 13, 2008, my staff discussed with Joanne Royce, of your staff, that FDA identified five gigabytes of electronic data that may be responsive to this request. As a suggestion, my staff invited Ms. Royce to FDA to review these electronic documents. Ms. Royce stated the committee would not require production or review of these documents. The enclosed documents conclude the Agency's response to this document request.

Information contained in the enclosures may include information that is trade secret, commercial confidential, privileged communication, or other information protected from disclosure to the public under the Freedom of Information Act (Title 5, *United States Code* [U.S.C.] 552), the Trade Secrets Act (18 U.S.C. 1905), the Privacy Act (5 U.S.C. 552a), and FDA regulations. The Committee should not publish or otherwise make public any such information. We would be glad to discuss with the Committee staff the protected status of any specific information.

We have restated your questions in bold, followed by our answer.

1) **Any and all records reflecting communication between Johnson & Johnson and FDA, FDA Office of Chief Counsel (OCC) or elsewhere within the Department of Health and Human Services (HHS) relating to advertising of Procrit between 1998 and 2005.**

   Responsive documents are enclosed.

2) **Any and all records reflecting communication between Amgen and FDA, OCC, or elsewhere within HHS relating to advertising of Aranesp, separately or bundled (for example with Neulasta or Neupogen)**

   Responsive documents are enclosed.

3) **Any and all records between Amgen and FDA, OCC, or elsewhere within HHS relating to "quality of life" claims including the claim that Aranesp may "relieve the symptoms of anemia" contained in the Aranesp package insert or label information.**

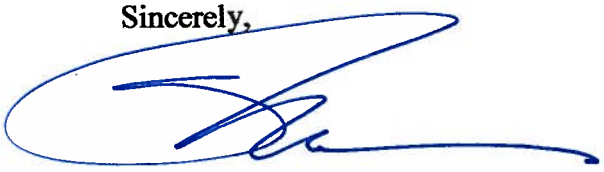
   Responsive documents are enclosed.

4) **Any and all records between Johnson & Johnson and FDA, OCC, or elsewhere within HHS relating to "quality of life" claims contained in the Procrit label, including the claim that "symptoms [of weakness, dizziness, chest pain] may improve" with use of Procrit.**

   Responsive documents are enclosed.

A similar letter has been sent to Chairman Stupak without enclosures. Thank you for your interest in this matter. If you have further questions, please let us know.

Sincerely,



Stephen R. Mason
Acting Assistant Commissioner
for Legislation

11 Boxes of Enclosures