DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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

APR 16 2008

Dear Mr. Chairman:

Thank you for the letter of March 6, 2008, co-signed by Chairman Bart Stupak, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, requesting that the Food and Drug Administration (FDA) discuss the overall safety of Erythropoiesis (EAS) at the March 13, 2008, Oncologic Drugs Advisory Committee (ODAC or the Committee) meeting.

As you know, to obtain marketing approval for a new drug, an applicant must demonstrate that the product is safe and effective, when administered in accordance with the approved product labeling. Specifically, there must be substantial evidence of effectiveness demonstrated in adequate and well-controlled clinical trials and FDA must find that the risks of the product do not outweigh the benefits.

FDA has been increasingly concerned with the safety signals observed in a number of clinical trials of ESAs. Due to this concern, there have been multiple labeling changes, advisory committee discussions, and public communications as the information evolved. At the March 13, 2008, ODAC meeting, the Committee discussed whether the demonstrated benefits of the ESAs outweigh the risks of increased mortality, blood clots, and tumor promotion in cancer patients. The Committee made the following recommendations:

- The Committee recommended that ESAs continue to be marketed for the treatment of chemotherapy-induced anemia in patients with cancer. (The Committee vote was: 13 yes to 1 no)
- The Committee recommended that the current indication should not be modified to restrict use only to patients with small cell lung cancer. (The Committee vote was: 8 no to 6 yes)
- The Committee recommended that the current indication should be modified such that ESAs are not indicated for patients receiving potentially curative treatments. (The Committee vote was: 11 yes to 2 no with 1 abstention)
- The Committee did not recommend a restricted distribution system (such as STEPS [thalidomide], RevAssist [lenalidomide], and iPLEDGE [isotretinoin]) for oncology patients receiving ESAs. (The Committee vote was: 10 no to 1 yes with 2 abstentions)

- The Committee recommended that, because increased tumor promotion and/or decreased survival have been duplicated in metastatic breast and head and neck cancer, the current label should be modified to remove these two cancer types from the indicated population. (The committee vote was: 9 yes to 5 no.)

The transcript of the ODAC meeting will be posted at:
http://www.fda.gov/ohrms/dockets/ac/cder08.html#OncologicDrugs.

Advisory committees are greatly valued by FDA and are considered a vital complement to the drug approval process. As you may know, advisory committee recommendations are not binding on FDA, but we consider them carefully when deciding drug issues.

We appreciate your interest in this important public health issue. Please be assured we intend to carefully consider what actions FDA should take to further evaluate and mitigate the risks of ESA treatment in cancer patients.

Thank you for contacting us concerning this matter. If we can be of further assistance, please let us know. A similar letter has been sent to Chairman Stupak.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations