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# U.S. House of Representatives
# Committee on Energy and Commerce
## Washington, DC 20515–6115

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March 12, 2008

The Honorable David M. Walker
Comptroller General
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Comptroller General Walker:

The Energy and Commerce Committee's Subcommittee on Oversight and Investigations held a hearing on the Food and Drug Administration (FDA) Science Board Subcommittee findings that the agency's mission is a risk. At the hearing on January 29, 2008, it became evident that FDA lacks the management capacity to carry out its responsibilities.

The Science Board Subcommittee report, entitled "FDA Science and Mission at Risk," recommended an infusion of resources—both in terms of dollars and staff. However, an open question is whether FDA has in place a strategic planning process to use such resources effectively. Under the Government Performance and Results Act of 1993, Congress required agencies to set long-term, results-oriented goals in their strategic plans and to use the results of the planning process to align activities, processes, and resources to accomplish the goals. Such strategic planning would provide a framework for establishing meaningful performance goals and measures, preparing credible budget requests, and facilitating congressional oversight of an agency's performance.

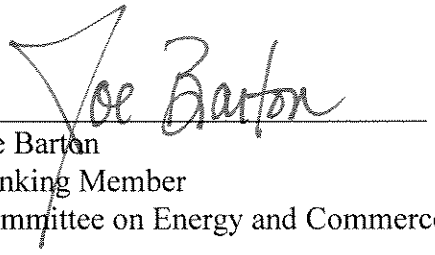
However, we are concerned that FDA strategic plans have become paper exercises and that their quality has diminished over recent years. We are also concerned that FDA managers are not fully committed to using these documents to align the agency's activities, processes, and resources.

We therefore ask the Government Accountability Office to review (1) the quality of FDA's strategic plan and the extent to which it addresses FDA's major responsibilities and management challenges, and (2) the extent to which FDA has aligned its program activities, management processes, and resources to accomplish its mission and strategic goals. We also ask

that you include in your review mission-critical program activities, import surveillance and inspection operations, and the field inspections of domestic and foreign drug or device facilities.

If you have any questions related to this request, please have your staff contact Peter Spencer of the Minority staff at 202-225-3641.

Sincerely,



Joe Barton
Ranking Member
Committee on Energy and Commerce

John Shimkus
Ranking Member
Subcommittee on Oversight and Investigations

cc: The Honorable John Dingell, Chairman
Committee on Energy and Commerce

The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations