1227 25th St., NW
Washington, DC 20037-1156

March 5, 2007

Division of Dockets Management [HFA-305]
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 21, rm. 3525
Rockville, MD 20993-0002

Re: [Docket No. 2006N-0525] Supplements and Other Changes to an Approved Application

Dear Sir or Madam:

The Combination Products Coalition ("CPC") respectfully submits these comments in response to the January 5, 2007, *Federal Register* Notice published by the Food and Drug Administration ("FDA") regarding *Supplements and Other Changes to an Approved Application: Public Meeting* (72 Fed. Reg. 574). The CPC is a group of leading drug, biological product, and medical device manufacturers with substantial experience and interest in the combination products arena. Because of its diverse, cross-industry membership, the CPC brings an unusually broad and unique perspective to the regulation of combination products. From that perspective, we offer these comments.

In response to the request for input on issues the agency should consider when evaluating and making changes to 21 C.F.R. § 314.70, we ask that the agency be mindful of the regulation's impact on marketing applications for certain combination products that have a drug or biological product as one component. More specifically, an approved New Drug Application ("NDA") may cover a product composed of a drug/device, biological product/device, or drug/biological product combination. We therefore ask that the agency be sensitive to how revisions to § 314.70 might impact these combination products. We further recommend that CDER involve the agency's Office of Combination Products in discussions about the revisions in order to ensure consistency among all relevant FDA regulations and policies.

The CPC also supports FDA's intention, as described in the Notice to modify the regulation to allow for a more flexible, risk-based approach to post-approval modification supplements. We believe that this approach is optimal for the drugs, biological products,

and combination products covered under the regulation. For example, the changes to enhance flexibility as described in the Notice should help encourage drug, biological product, and combination product manufacturers (as applicable) to make needed manufacturing and product changes in an efficient manner while also protecting patient safety. Additionally, the regulatory landscape for combination products continues to evolve in response to the rapid technological advances that are occurring with these products. We therefore believe that the regulation should set forth general parameters for post-approval modifications, and that more specific approaches should evolve through guidance documents developed under the agency's Good Guidance Practices. Such an approach will allow the combination product regulatory scheme to evolve appropriately.

In summary, the CPC applauds FDA for its efforts to develop a more flexible and risk-based approach to the regulation governing supplements and other changes to approved marketing applications for drugs and certain biological products. Please do not hesitate to contact us if we can assist the agency in addressing specific issues or questions relating to combination products.

Respectfully submitted,

Bradley Merrill Thompson,
On behalf of the Combination Products Coalition

cc: Mark Kramer