Children's Health Protection Advisory Committee

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March 3, 2005

Stephen Johnson, Acting Administrator United States Environmental Protection Agency 1200 Pennsylvania Avenue Washington, D.C.

RE: Release of Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens

Dear Acting Administrator Johnson:

The Children's Health Protection Advisory Committee (CHPAC) discussed the status of the Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens at our recent meeting. We appreciate the efforts the Agency has made in addressing the important topic of carcinogen exposures in early life. We are writing you now to urge release of the Supplemental Guidance concurrently with the Guidelines for Carcinogenic Risk Assessment. At our meeting, we learned from EPA staff that the Guidelines for Carcinogenic Risk Assessment must be released March 15, 2005 to coincide with the residual risk rule for coke oven emissions¹. However, the revised Supplemental Guidance, which addresses the cancer risk from early-life exposures, has not yet been cleared for release. This could result in the Supplemental Guidance being decoupled from the main Guidelines. The primary guidelines, if issued alone, would not adequately address the issue of early-life exposures to carcinogens. This would be regrettable since an earlier SAB review of the cancer guidelines was critical of inadequate consideration of the potential elevated cancer risks from early-life exposure to carcinogens. In addressing this criticism, EPA spent considerable effort developing the Supplemental Guidance. It has now gone through ample and extensive peer review and the basic

¹ Clean Air Act Section 112.0.7

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conclusions remain unchanged. All effort should be made to release the Supplemental Guidance along with the primary carcinogenic risk assessment guidelines. We thank you for your consideration of this important issue.

Sincerely,

Melanie A. Marty, Ph.D., Chair

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Cc: Michael Leavitt, Secretary, U.S. Department of Health and Human Services Andrew C. von Eschenbach, Director, National Cancer Institute Dr. Elias A. Zerhouni, Director, National Institutes of Health Vice Admiral Richard H. Carmona, U.S. Surgeon General Timothy Oppelt, Acting Assistant Administrator, U.S. EPA Office of Research and Development

Al McGartland, Director, U.S. EPA Office of Policy, Economics, and Innovation William Farland, Acting Deputy Assistant Administrator, U.S. EPA Office of Research and Development