REPORT OF THE SCIENTIFIC ADVISORY BOARD FOR NEW PRODUCT DEVELOPMENT
14 July 2006

In 1996, Philip Morris USA established a panel of external scientific advisors (the Scientific Advisory Board, SAB) to evaluate the design and conduct of studies of new products, including an electrically heated cigarette smoking system (ECHSS) that heated but did not burn the tobacco of a uniquely designed cigarette. The SAB included recognized experts in analytical chemistry, biochemistry, clinical medicine, pathology, pharmacology, statistics, toxicology, and veterinary medicine.

The SAB independently and collectively evaluated the design and the implementation of the preclinical studies and the clinical trials of this novel smoking system, and compared the chemical composition and the biological activity of its smoke to conventional cigarettes. The test protocols were appropriate to assess the chemical composition and biological activity of tobacco smoke. The SAB unanimously concluded that the study designs (protocols) were consistent with generally accepted principles of toxicology and experimental design and are consistent with internationally recognized scientific and regulatory guidelines for safety evaluation, (e.g. USFDA and OECD). As part of its critical assessment of the implementation of the preclinical studies, the SAB visited the testing facilities in the United States and Europe (Cologne, Germany and Brussels, Belgium). The SAB unanimously concluded that the testing facilities met Good Laboratory Practices (GLP) regulations.

The SAB independently and collectively evaluated the preclinical data and unanimously concluded that the findings demonstrated reduced levels of most smoke constituents and reduced biological activities on a per cigarette basis.

The SAB evaluated the design of the human clinical studies (8-day short- term exposure and 12-week longer-term exposure) and concluded that the design of these studies was consistent with current clinical guidelines (ICH (1)). The SAB did not visit the human clinical trial sites.

The SAB independently and collectively evaluated the clinical data and unanimously concluded that the findings (biomarkers of exposure in humans) in the EHCSS decreased in short- and longer-term studies, compared to conventional cigarettes.

An SAB member (RAL) and an external auditor conducted quality assurance audits as an important component of the overall assessment of selected studies. Both auditors concluded that there was compliance with U.S. and European standards (eg. USFDA (2) and OECD (3).

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The SAB unanimously concludes that the EHCSS is a reduced exposure product on a per cigarette basis.

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Citations

1) ICH, 1996
2) USFDA, 21 CFR Part 58.
3) OECD. GLP. Monograph No. 45. Paris, France, 1992

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