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FABA Malaysia Chapter launched

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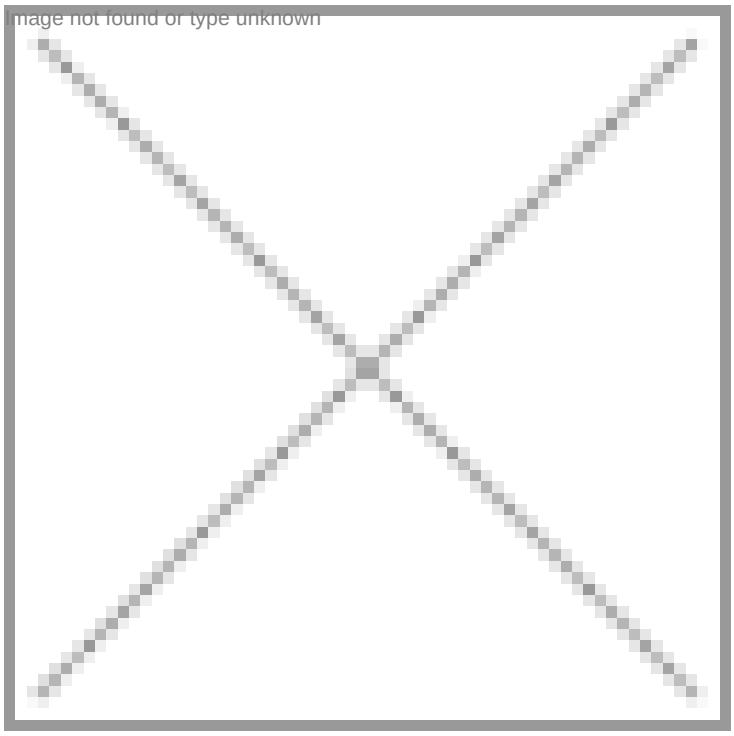

FABA Malaysia Chapter launched

The Malaysia Chapter of the Federation of Asian Biotech Associations (FABA) was officially launched during the Biotechnology Asia 2006 Exhibition and Conference held recently at the Putra World Trade Center in Kuala Lumpur. The Chapter will be headed by Abdul Latif Ibrahim, Director of Universiti Industri Selangor and biotechnology advisor to the Selangor State
Government.

FABA, which aims to safeguard the overall interest of biotechnology as a science and profession within the industry, and to promote it within member countries, was formed during "BioAsia 2004" held at Hyderabad in India. Other FABA member countries are Iran, Israel, Pakistan, India, the Philippines, Saudi Arabia, Singapore, Sri Lanka, Thailand, South Korea, Japan, and Indonesia.

Source: www.isaaa.org

Joint Taskforce proposes guidelines to improve early stage clinical trials

Following the TGN1412 clinical trial at Northwick Park, a joint industry taskforce set up by the Association of the British Pharmaceutical Industry (ABPI) and the BioIndustry Association (BIA) has proposed recommendations to enhance and clarify the existing guidelines governing the testing of new medicines in humans.

The taskforce recommendations, which are based on existing best practice within industry, have been submitted to the scientific expert group chaired by Prof. Gordon Duff reviewing early stage clinical trials. Specific recommendations include: use of an alternative initial dose-setting assessment for certain novel agents, giving only one subject the active medicine on the first day, following this with "staggered dosing" as doses are increased, conducting such studies at a hospital with intensive care facilities, providing all investigators with appropriate training in such studies, giving particular emphasis to manufacturing controls to ensure safety, quality and efficacy of the finished product.

"As a responsible industry, we were shocked and want to ensure a similar event never occurs again, and that is why we have developed these 'points to consider' for first-in-human clinical studies. In order to safeguard patient safety, we want to make the guidelines available to the research-based industry and, if either the UK or the European regulatory bodies find this useful, to help develop them into a more formal set of points to consider," said Dr David Chiswell, one of the co-chairmen of the taskforce.

The taskforce carefully examined existing regulatory guidance for biopharmaceuticals. The ABPI and BIA set up their joint taskforce to provide industry input into Prof Gordon Duff's expert working group established to learn from the TGN1412 clinical trial adverse events. Membership of the group comprised bioscience and pharmaceutical industry experts.

Source: www.bioindustry.org

Sri Lanka approves GM legislation

The Sri Lankan government has approved a law that requires all genetically modified (GM) food items to be prominently labeled. The legislation will come into effect from January 1, 2007. All GM food importers will also be required to apply for a permit from the Food Advisory Committee, chaired by the health services director general, to import GM products in the future. A permit will be issued only after the GM product is verified as safe for human consumption, and with the condition that the product will be properly labeled.

Source: www.isaaa.org

ABAC gets new members

Australian industry minister, Ian Macfarlane, has announced the appointment of four new members to the Australian Biotechnology Advisory Council (ABAC). The ABAC plays an important role in providing independent expert advice to the government on high-priority issues influencing the adoption of biotechnology in Australia

The new appointees include Prof. Linda Blackall, research director of the Environmental Biotechnology Cooperative Research Centre, Dr Jonathan Izant, executive director of the Institute of Health and Biomedical Innovation at QUT, John Lush, a farmer and well known Grains Industry leader and Dr Peter Riddles, member of the Queensland Biotechnology Advisory Council and on the board of several biotech firms.

Welcoming the new members, Ian Macfarlane said, "The new appointees are all experts in their fields and are highly regarded within the international biotechnology community. The mix of skills will ensure ABAC continues to provide quality, scientific advice to the government."

The five retiring members of ABAC include Dr Deborah Rathjen, Prof. John Hearn, Hugh Roberts, Prof. Peter Andrews and Dr Julia Playford.

Source: www.biotechnology.gov.au