

Background Information

Nonclinical Studies Subcommittee Advisory Committee on Pharmaceutical Science September 9-10, 2002

The chairs of the expert working groups on biomarkers of cardiotoxicity and biomarkers of vascular injury will report on the progress and activities of their groups since the last meeting of the Subcommittee. Both groups have initiated written reports, and will present their proposed points of discussion and conclusions to the Subcommittee for discussion and feedback prior to preparation of their draft reports. Information relevant to the key points of discussion identified by these expert working groups is appended:

1. Table of potential biomarkers of vascular injury and key discussion points
2. Outline of the discussion points on biomarkers of cardiac injury.

The expert working group on biomarkers of vascular injury expects to have a preliminary written draft available prior to the meeting, and this will be made available to the Subcommittee and interested parties via the FDA website www.fda.gov/cder/audiences/acspage/acslst1.htm when it becomes available.

The Subcommittee will also discuss a proposal to transfer oversight of the Subcommittee from the Advisory Committee for Pharmaceutical Science to the Science Advisory Board of the National Center for Toxicological Research. A summary of the rationale and proposed structure is appended.