

Panel Recommendation Options

For

Premarket Approval Applications

The Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (Act), as amended by the Safe Medical Devices Act of 1990, allows the Food and Drug Administration to obtain a recommendation from an expert advisory panel on designated medical device pre-market approval applications (PMAs) that are filed with the Agency.

The PMA must stand on its merits, and the Panel's recommendation must be supported by safety and effectiveness data in the application, or by applicable, publicly available information. **SAFETY** is defined in the Act as reasonable assurance, based on valid scientific evidence, that the probable benefits to health {under conditions of intended use} outweigh any probable risks. **EFFECTIVENESS** is defined as reasonable assurance that, in a significant portion of the population, the use of the device for its intended uses and conditions of use {when labeled} will provide clinically significant results.

The Panel's recommendation options for the vote are as follows:

- 1. APPROVAL.** There are no conditions attached.
- 2. APPROVABLE with conditions.** The Panel may recommend that the PMA be found approvable subject to specified conditions, such as physician or patient education, labeling changes, or further analysis of existing data. Prior to voting, each of the conditions should be discussed and voted on by the Panel.
- 3. NOT APPROVABLE.** The Panel may recommend that the PMA is not approvable if:
 - the data **DO NOT** provide a reasonable assurance that the device is safe,

OR

- the data **DO NOT** provide a reasonable assurance that the device is effective,
under the conditions of use prescribed, recommended, or suggested in the proposed labeling.

Following the voting, the Chair will ask each panel member to present a brief statement outlining the reasons for their vote.

Revised: December 10, 2004