

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 premarket approval applications (PMAs) that are filed with the Agency. The PMA must stand on its own merits and your 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 on 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.

Your recommendation options for the vote are as follows:

1. **APPROVAL** – If 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 a further analysis of existing data. Prior to voting, all of the conditions should be discussed 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.

Voting Procedures

- Chair asks for a motion for (a) approval, (b) approvable with conditions, or (c) not approvable.
- A voting member makes a motion recommending an action.
- The Chair requests a second on the motion.
- The Chair entertains discussion.
 - If the motion is for approvable with conditions, then...
 - Chair asks for a motion for an individual condition and a second.
 - The individual condition is discussed.
 - The individual condition is voted on by polling.
 - Additional conditions are handled the same way.
- The Chair calls for a vote on the motion. If the motion is for approvable with conditions, then the entire amended motion is voted on.
- Voting is accomplished by polling.
- After the voting is complete, each panel member is asked to state for the record the rationale for his/her vote. If the panel member voted for disapproval, then he/she should indicate what is needed to make the PMA approvable. The Consumer and Industry Representatives also state their opinions at this time.

Note: PMA review is INDEPENDENT of the following considerations:

- Cost
- Previous regulatory difficulties
- Clinical data submitted in other PMAs for similar devices by competing companies
- Medicolegal climate and its effect on the standard of care