Important Changes to FDA Expert Panel Review of Premarket Devices

May 4, 2010

On April 26, 2010, the U.S. Food and Drug Administration (FDA) announced important changes to the process used by the Medical Device Advisory Committees for devices under premarket review. These changes became effective on May 1, 2010. The increasing number of advisory panel meetings at the Center for Devices and Radiological Health (CDRH) prompted the changes. CDRH also recently centralized and expanded the advisory committee staff to improve continuity across the Center.

The following table summarizes the previous panel process, FDA’s changes to the process, and FDA’s rationale for the changes:

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<tr>
<th>PREVIOUS PANEL PROCESS</th>
<th>CHANGE TO PANEL PROCESS</th>
<th>FDA’S RATIONALE FOR THE CHANGE</th>
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<td>The panel voted on the device’s approvability and the conditions of approval.</td>
<td>The panel will vote on the device’s safety and effectiveness, and the device’s risk versus its benefit.</td>
<td>In the past, the final vote of the panel on the device’s approvability did not always reflect the substance of the panel’s discussions. The changes to the process will allow the panel to focus on issues relating to their medical and scientific expertise, rather than on regulatory issues such as the requirements for approvability.</td>
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<td>FDA’s presentations to the panel included comments on the device’s approvability.</td>
<td>FDA’s presentations to the panel will no longer include comments on the device’s approvability.</td>
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<td>The panel voted by a show of hands.</td>
<td>The panel will vote by electronic ballot. The votes will be publicly tallied so that panel members can be identified by their vote.</td>
<td>The ballot process will allow each panel member to cast a vote without the potential influence of seeing the other members’ votes.</td>
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<td>No prohibition of FDA seeking clarification or asking questions of the panel during panel deliberation or discussion of FDA questions.</td>
<td>CDRH will instruct the panel to provide their opinions and recommendations to FDA’s questions without interruption. The panel will have one hour for deliberations, during which panel members may ask questions of the sponsors and FDA.</td>
<td>This change will allow the panel more time to discuss the issues without interruption and will foster robust discussion.</td>
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CDRH reviewers presented an analysis of the supporting data that reflected a consensus of their opinions.

CDRH reviewers will present the range of their scientific opinions.

This change will foster a more in-depth discussion on the device’s safety and effectiveness, the device’s risks and benefits.

The first change described above is likely to diminish the influence of the advisory committees. In the past, FDA asked the panel if the PMA provided a reasonable assurance of safety and effectiveness. This was a straightforward question. With the change, FDA will be able to formulate questions that may make it more difficult to obtain a favorable vote from the panel. This is likely to occur in those circumstances where the FDA staff disagrees with the applicant as to whether the PMA should be approved. Without the panel’s vote on the standard questions for approvability, FDA will have greater flexibility in formulating questions that suit their needs. This change could ultimately prove very detrimental for the industry.

Moreover, additional changes to the panel process may be forthcoming. FDA’s premarket review of devices remains a focus of congressional debate and public critique. FDA indicated that the Agency “will continue to evaluate panel procedures and make changes when necessary.”

If you have any questions about the panel process, please contact us.

For more information, contact:

Edward Basile                 Laurie Clarke              Elaine Tseng             Marian Lee                     Lynette Zentgraft
+1 (202) 626 2903             +1 (202) 626 2645          +1 (415) 318 1240          +1 (202) 661 7955          +1 (202) 626 2996
ebasile@kslaw.com             lclarke@kslaw.com          etseng@kslaw.com          mlee@kslaw.com             lzentgraft@kslaw.com

King & Spalding

Washington, D.C.
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 (202) 737-0500
Fax: +1 (202) 626-3737

San Francisco, CA
101 Second Street
Suite 2300
San Francisco, CA 94105
Tel: +1 (415) 318-1200
Fax: +1 (415) 318-1300

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