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Client Alert

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FDA Announces Improved Policies for Advisory Committees

On August 4, 2008, the Food and Drug Administration announced several improved policies and procedures strengthening its management of FDA advisory committees. FDA advisory committees are panels of independent, outside experts -- often the world's leading authorities in their fields -- who advise agency officials as they consider regulatory decisions involving complex medical and scientific issues. FDA may pose questions to an advisory committee about a specific product. The advisory committee discusses the questions after reviewing briefing materials that contain background information such as available clinical studies and then votes on the questions presented by FDA. Although the committee makes recommendations to FDA, the agency makes the final decisions.

Advisory committees play an important role in strengthening the science that supports medical product safety—from analyzing questions of benefit and risk to evaluating data used to detect and communicate safety problems. FDA currently has 48 technical and scientific advisory committees. A committee generally includes a chairperson, several scientists and health professionals, an industry representative, a consumer representative, and sometimes a patient representative. Last year FDA convened meetings of advisory committees on topics ranging from the safety of diabetes medications to the evaluation of new anticancer drugs for use in children.

The release of these guidance documents will bring greater transparency and public disclosure to the work of advisory committees by imposing stricter limits on financial conflicts of interest for committee members, enhanced voting procedures, and more disclosure of information pertaining both to advisory committee members and to specific matters considered at advisory committee meetings. Although guidance documents are not legally enforceable, they describe FDA's current thinking on a topic. Therefore, FDA employees may depart from a guidance document only with appropriate justification and supervisory concurrence.

The new procedures are described in four final guidance documents and a proposed clarification of when FDA should refer a matter to an advisory committee is described in a draft guidance. All of the guidances are available on FDA's website (http://www.fda.gov/oc/advisory/). Most of the changes in the final guidance documents will go into effect immediately, and all are expected to be fully implemented by the first of December 2008.

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Evaluating and Disclosing Information Concerning Conflicts of Interest and Financial Interest of Advisory Committee Members

Two of the guidance documents address one of the most contentious issues involved in the advisory committee process—conflicts involving committee members and FDA's processes for evaluating and disclosing information about potential conflicts of interest. FDA has long acknowledged that finding experts free of financial conflicts is difficult because many respected and qualified physicians and academics serve as industry consultants, receive grants, or have stock holdings and contracts with companies that will be affected by an advisory committee's recommendations. Under the new guidance, FDA is instituting a cap of $50,000 as the maximum personal financial interest an advisor may have in all companies that may be affected by a particular meeting. If an advisor's personal financial interest is greater than $50,000 (including the individual advisor, his or her spouse, and minor children), he or she will not be allowed to participate in that meeting.

If less than $50,000, FDA officials may, in certain situations, grant a waiver, but will do so only if they determine that there is an essential need for the advisor's particular expertise. No waiver will be issued when the advisor is the principal investigator of a clinical trial of a product that is the subject of the committee meeting. Any waivers issued by FDA will disclose the advisor's personal financial interest and why the need for the expertise was essential and will be posted on the FDA's web site in advance of the meeting. FDA intends to use new templates for waivers and financial interest disclosure that will make them clearer and more consistent.

Public Availability of Information Given to Advisory Committee Members

Another improvement addresses the public availability of briefing materials, the background information provided to advisory committee members in advance of a meeting. FDA will post briefing materials given to advisory committee members on the FDA's web site at least 48 hours before the meeting is scheduled to occur. The guidance document provides details on preparing and submitting documents to FDA for inclusion in the briefing materials, and also recommends a timetable that sponsors should follow when submitting such documents.

Voting Procedures

The agency also issued recommendations addressing the way that advisory committees will vote on questions before the advisory committee. These improvements are being implemented to avoid even the perception of any manipulation of votes. FDA recommends that advisory committees use a process of simultaneous voting, in which all members vote at once. Previously, advisory committees sometimes voted sequentially, with the committee chair calling on each member individually and asking them to announce their vote aloud. The rationale for this recommendation is that simultaneous voting avoids "voting momentum" in which some voters may be influenced, even subconsciously, by the votes of those who precede them. The agency also recommends that the results of votes be announced immediately in the meeting, and

FDA intends to post on the FDA website a list indicating how each member voted. Any posted list will be part of the permanent record of the meeting.

Clarification of When FDA Should Refer a Matter to an Advisory Committee

FDA also issued a draft guidance for public comment that establishes new criteria for when the agency should refer a matter to an advisory committee. In some instances FDA is required by law to refer a matter to an advisory committee. In other instances, FDA would consider these new criteria when deciding whether to refer a matter to an advisory committee. The purpose of this proposed change is to make FDA's advisory committee process more predictable and transparent.

Web Site Improvements

The agency also made improvements to the advisory committee web site to make it easier for users to access news on advisory committee meeting dates, agendas, financial disclosures and briefing materials. These enhancements include quick access to upcoming meetings and meeting materials, past meeting information, and a new section titled "Most Popular" to link the user to significant areas of public interest.

For more information regarding FDA advisory committees, please contact William H. Kitchens.