

## *ACNP Council Endorses FDA Guidance on Advisory Committees*

The FDA published guidances relating to the functioning of advisory committees in the Federal Register on August 5, 2008. The ACNP Executive Committee submitted comments endorsing these guidance statements and applauding FDA for this action.

These guidance statements provide clarity and transparency regarding the vitally important matters of conflict of interest of advisory committee members and the public disclosure of advisory committee members' financial information. The guidances provide a procedure for simultaneous voting by advisory committees that protects against the "momentum" that can inappropriately influence the outcome of a vote in a sequential voting process. Finally, these guidances provide more clarity for industry sponsors in producing briefing materials for advisory committees and in making that information publicly available. ACNP applauds FDA for providing these guidance documents that will enhance the transparency, the consistency, and the integrity of the advisory committee process. Below is a list of these guidance statements. Each may be found on at <http://www.fda.gov/oc/advisory/newacguidance0808.html>

- "Guidance for the Public and FDA Staff on Convening Advisory Committee Meetings"--This draft guidance provides clarity on when the FDA should consider referring a matter to an advisory committee. The College submitted comments endorsing this guidance.
- "Voting Procedures for Advisory Committee Meetings"--This final document provides structure for advisory committee voting procedures. This guidance is effective as of August 5, 2008.
- "Guidance for Industry: Advisory Committee Meetings--Preparation and Public Availability of Information Given to Advisory Committee Members"--This final document provides information to industry sponsors, applicants and petitioners who develop, prepare or submit briefing materials that will be given to advisory committee members as background information before an open advisory committee meeting. The effective date of this guidance is August 5, 2008.
- "Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees"--This document describes the factors and analyses that should be used in determining whether an advisory committee member has a potential conflict of interest and whether participation in a meeting is appropriate. This guidance is effective for FDA advisory committee meetings scheduled on or after December 3, 2008.
- "Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers"--This document provides guidance on FDA procedures regarding public availability of information regarding certain financial interests and waivers granted by the FDA to permit individuals to

participate in an advisory committee meeting. This guidance is effective as of August 5, 2008.