U.S. Department of Justice
Office of the Solicitor General

Washington, D.C. 20530

January 16, 2008

Honorable William K. Suter
Clerk
Supreme Court of the United States
Washington, D.C. 20543

Re: Riegel v. Medtronic, Inc., No. 06-179
Warner-Lambert Co., LLC v. Kent, No. 06-1498
Wyeth v. Levine, No. 06-1249

Dear Mr. Suter:

The Solicitor General filed an amicus brief on behalf of the United States in all three of these cases, which involve questions of preemption under the Federal Food, Drug, and Cosmetic Act. The purpose of this letter is to inform the Court that the Food and Drug Administration published a Notice of Proposed Rulemaking in the Federal Register today that may be relevant to these cases.

The notice, entitled Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, is published at 73 Fed. Reg. 2848. As the Federal Register notice explains, the proposed rule would "amend [the agency's] regulations regarding changes to an approved new drug application (NDA), biologics license application (BLA), or medical device premarket approval application (PMA) to codify the agency's longstanding view on when a change to the labeling of an approved drug, biologic, or medical device may be made in advance of the agency's review of such change." Ibid. Under the proposed rule, a supplemental application submitted under those provisions is appropriate "to amend the labeling for an approved product only to reflect newly acquired information," and may "add or strengthen a contraindication, warning, precaution, or adverse reaction only if there is sufficient evidence of a causal association with the drug, biologic, or device." Ibid.

I would appreciate it if you would circulate this letter and copies of the enclosed Federal Register notice to the Members of the Court. Thank you for your assistance with this matter.

Sincerely,

Paul D. Clement
Solicitor General

cc: All counsel of record