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January 9, 2008

Ms. Marcia M. Waldron, Clerk
United States Court of Appeals for the Third Circuit
21400 U.S. Courthouse
601 Market Street
Philadelphia, PA 19106-1790

Re: *Joseph C. Colacicco v. Apotex Inc.*, No. 06-3107 (3d Cir.)

Dear Ms. Waldron:

Pursuant to Fed. R. App. P. 28(j), the United States submits this letter and respectfully requests that copies be forwarded to Judges Sloviter, Ambro, and Restani, before whom the case was argued on December 10, 2007.

On December 21, 2007, the United States filed an amicus brief in *Wyeth v. Levine*, No. 06-1249 (S. Ct.) (copy attached). That brief sets out the Food and Drug Administration's position (at 8-12) that state tort claims are preempted to the extent they would impose liability for a drug manufacturer's use of labeling that FDA approved after being informed of the relevant risk. The brief also explains (at 13-14) that, as construed by FDA, 21 C.F.R. § 314.70 is limited to labeling changes based on "material new information" and does not permit changes based on information that was previously available to FDA. FDA's views are relevant to the preemption issue posed by this case.

In addition, the United States seeks to correct the misstatement in appellant's 12/26/07 letter that FDA lacks authority "to reject a company's strengthened prescription drug label" or to dictate the content of a prescription drug label. Federal law prohibits the marketing of a prescription drug if its labeling is false or misleading or does not bear adequate directions for use. *See* 21 U.S.C. §§ 331(a), (k), 352(a), (f). FDA's longstanding position is that labeling statements, including warnings, that are not adequately supported by scientific evidence are false and misleading. *See, e.g.*, 44 Fed. Reg. 37,434, 37,434, 34,755 (1979); 71 Fed. Reg. 3922, 3934 (2006). FDA may refuse to approve a drug, *see* 21 U.S.C. § 355(d)(7); 21 C.F.R. § 314.125(b)(6), or withdraw approval of an already-approved drug, *see* 21 U.S.C. § 355(e); 21 C.F.R. § 314.150(b)(3), if its labeling is false or misleading. FDA may also seek *in rem*

forfeiture of the drug and/or an injunction barring its distribution. *See* 21 U.S.C. §§ 334, 332(a). A manufacturer is also subject to criminal prosecution for distributing a misbranded drug. *See id.* § 333(a). FDA utilizes this statutory and regulatory authority to determine the content of prescription drug labeling.

Very truly yours,

Sharon Swingle

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