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Mr. Robert F. Green
Leydig, Voit & Mayer, Ltd.
Two Prudential Plaza, Suite 4900
Chicago, Illinois 60601-6780

Re: Docket Nos. 98P-1035/CP1 and 98D-0265

Dear Mr. Green:

This letter responds to your citizen petition dated November 19, 1998, requesting that the Food and Drug Administration (FDA) not apply section 505A of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 355a) to the over-the-counter (OTC) drug Zantac 75. Your petition is denied for the following reasons.

Section 505A of the Act applies to applications submitted under section 505(b) of the Act (21 U.S.C. 355a(a) and (c)), regardless of whether a drug is a prescription or OTC drug. The plain language of the Act does not limit the type of section 505(b) applications that may earn pediatric exclusivity. Your discussion of the legislative history of this section of the Act does not change the plain language of the Act. The plain language of the Act is consistent with the legislative intent of the Act to offer pediatric exclusivity as an incentive to obtain pediatric studies on all drugs, including OTC drugs. The mere fact that a drug is marketed OTC does not mean it is not used in the pediatric population. Moreover, Congress conventionally distinguishes prescription drugs from OTC drugs by referring to section 503(b) of the Act (see, e.g., section 801(d)(1) of the Act (21 U.S.C. 381(d)(1))). Congress did not include such a reference in section 505A, indicating that it did not intend to limit application of the section to prescription drugs.

Zantac 75 was approved under section 505(b) of the Act. Section 505A of the Act applies to applications submitted under section 505(b) of the Act. Therefore, Zantac 75 maybe eligible to receive pediatric exclusivity under section 505A of the Act . Accordingly, your petition is denied.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

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98D-0265