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Food and Drug Administration  
Rockville MD 20857

Ms. Leslie Koehler  
Manager, Regulatory Affairs  
Hospital Products Division  
Abbott Laboratories  
Dept. 389, Bldg. AP30  
200 Abbott Park Road  
Abbott Park, IL 60064-6157

Re: Docket Nos. 99P-2850/CP1 and 98N-0056

Dear Ms. Koehler:

This letter responds to your citizen petition dated August 13, 1999, in which you request that the Food and Drug Administration (FDA) add paricalcitol to the priority section of the List of Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population (Docket No. 98N-0056). The Agency has evaluated your petition and concluded that paricalcitol meets the criteria for inclusion on the priority section of the list. Accordingly, your petition is granted. FDA will add paricalcitol to the priority section of the list for the indication prevention and treatment of secondary hyperparathyroidism associated with chronic renal failure.

This addition is effective as of the date of this letter. If you submit a Proposed Pediatric Study Request before the list is physically updated, please include a copy of this letter with your proposal to ensure your proposal is reviewed in the proper order.

Sincerely yours,

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

99P-2850

PAV1

## CROSS FILE SHEET

File Number: 99P-2850/PAY1

See File Number: 98N-0056/LET12