



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 27 2006

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Charles R. Nolan, M.D.
7703 Floyd Curl Drive
San Antonio, Texas 78229-3900

Docket No. 2006P-0186/CP1

Dear Dr. Nolan:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received May 4, 2006. You request that FDA withdraw the New Drug Application (NDA 21-179) for Renagel Tablets (sevelamer hydrochloride), 400 and 800 milligrams, marketed by Genzyme Corporation, because of the association of this drug with intestinal obstructions and perforations in dialysis patients. Alternatively, you request that FDA require a "black box" warning about the risk of intestinal obstruction and perforation in the labeling for Renagel Tablets and require that Genzyme Corporation disseminate a "Dear Doctor" letter to inform the healthcare community of the labeling changes.

FDA has been unable to reach a decision on your petition because it raises significant and complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0186

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