

Gordon M. Binder  
Chairman of the Board

**AMGEN**

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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

In response to your request for comments on changing FDA policy for prescription to OTC switches, I offer the following:

Switches should not be made without a request from the company unless the switch can be made using the dose level and dosage form of the prescribed product. If switches are approved for a reduced dose or different dosage form at company request, sufficient clinical trials should be required to establish that the reduced dose is efficacious. I believe that some switches have been made at doses so far below the prescribed dose that patients are relying on a product whose dose is too low to provide real efficacy. This is misleading and is not in the best interest of a patient's well-being.

Any switch made without a company request should provide at least one year's advance notice of the effective date. In some cases the revenue reduction resulting from a switch will be high enough that layoffs will be required. Longer notice would give companies time to reduce hiring, retrain workers, encourage early retirements and otherwise reduce the adverse impact on employees and their families. The shorter the notice period the bigger the potential layoff.

OTC patients rarely read warning information and absent advice from a doctor or pharmacist should not be exposed to dangerous side effects, even for a very small percentage of patients.

Conversion to OTC normally results in a company decision to eliminate all, or nearly all, future clinical trials. If involuntary conversions were made, this disadvantage should receive careful consideration. It has been about ten years since Amgen's first two drugs were approved and we still are doing meaningful clinical trials today.

There is a serious Constitutional question regarding FDA's authority to force companies to do any clinical trials or any other work to support an OTC switch that was not requested by the company. Even if the government paid for the work, a serious question of law would remain.

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Prescription to OTC switching is a very important issue. I appreciate the opportunity to comment and look forward to your final decision.

Sincerely,

A handwritten signature in black ink, appearing to read "Gordon M. Binder". The signature is fluid and cursive, with a prominent initial "G" and a long, sweeping underline.

Gordon M. Binder  
Chairman of the Board