

January 18, 2002

Mr. Daniel Troy  
Chief Counsel  
Food and Drug Administration  
Room 6-57 (GCF-1)  
5600 Fishers Lane  
Rockville, Maryland 20857-1706

Dear Mr. Troy:

The Generic Pharmaceutical Association (GPhA) submits the attached document which responds to your request for materials that will be used in a meeting scheduled for January 30, 2002 with various industry representatives. GPhA's members are looking forward to making progress on resolving serious problems with the regulatory and statutory framework which governs the review and approval of abbreviated new drug applications by the Food and Drug Administration (FDA). We believe that framework has become seriously flawed in its application of both legislative intent and the plain meaning of the statutory language. As a result, consumers are denied timely access to safe and effective generic medicines.

We wish to emphasize that it is our view the FDA cannot unilaterally resolve all of the problems which presently impede consumer access to generic medicines. Changes in technology and research methodologies, and a variety of legal strategies used by regulated companies since the enactment of the Hatch-Waxman Act have required FDA and the Courts to make piecemeal adjustments to the Act. Cumulatively, these changes have produced a nearly impossibly complex and contradictory review process that is unpredictable and subject to manipulation and abuse. The system begs for a more thorough reform than is possible through simply revising existing regulations and policies.

GPhA welcomes the dialogue you have invited our industry to participate in, and we strongly believe that some interim regulatory changes are needed and should be implemented. However, there is a real danger that the process of engaging in this dialogue could be used by some industry representatives as a justification to delay legislative reforms which otherwise would be considered and implemented by the U.S. Congress. FDA should exercise care that GPhA's discussions with you not have the appearance of, or become an actual impediment to, legislative reforms that are needed to address critical elements of the generic drug approval process. In particular, we are concerned that the discussions may be used by the brand industry who benefit from the

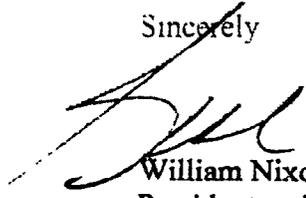
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present dysfunctional regulatory and statutory framework to argue that Congress should delay doing what needs to be done on the premise that any problems are being handled adequately at the administrative level.

To prevent our dialogue with you from being misinterpreted in this way, GPhA urges FDA to issue a statement that regulatory changes, while needed, cannot address basic problems inherent in the statutory scheme. FDA's statement should make clear that the dialogue you have initiated cannot be, and should not be viewed as, a substitute for needed legislative reform, or as a reason for Congress to defer consideration of proposed legislation to achieve that goal.

We look forward to discussing the regulatory improvements described in the attached submission.

Sincerely



William Nixon  
President and CEO