DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

October 6, 2006

Steven Stone, M.D.
President
American Academy of Dermatology
P.O. Box 4014
Schaumburg, IL 60618-4014

Dear Dr. Stone,

Today, FDA and the manufacturers of isotretinoin will announce an important change to iPLEDGE, the risk management program for isotretinoin. This change is intended to increase the efficiency of access to isotretinoin for patients enrolled in iPLEDGE. Today's change involves the elimination of the 23-day lockout period for males and females of non-childbearing potential who are prescribed isotretinoin. Previously, all patients were required to fill their isotretinoin prescription within 7 days of their office visit. If more than 7 days had elapsed, patients would need to requalify for a new prescription and wait 23 days before it could be filled. This 23 day lockout period will no longer be required for males and females of non-child bearing potential who are prescribed isotretinoin.

FDA would like to take this opportunity to thank the AAD for its continued efforts to bring the concerns of patients and prescribers to our attention. Your organization has provided us with important insights into the real world in which dermatologists practice and patients are treated. We appreciate your constructive comments over the past several months regarding the iPLEDGE program, especially those related to potential improvements in program efficiency.

FDA remains strongly committed to ensuring the success of iPLEDGE, implementing effective risk management while maintaining patient access to isotretinoin therapy. We look forward to your continued support of these goals.

Sincerely,

Susan Walker, MD
Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research