



JAN 11 2002

Food and Drug Administration
Rockville MD 20857

4855 '02 JAN 18 P2:29

Andrew N. Gustafson, Ph.D.
Vice President, U.S. Regulatory Affairs
GlaxoSmithKline
Five Moore Drive
Research Triangle Park, NC 27709

Re: Docket Number 01P-0268/CP1

Dear Dr. Gustafson:

This responds to your citizen petition, dated June 12, 2001, requesting that FDA remove the black box from the labeling for inhaled corticosteroid drug products. The black box surrounds the warning about the risk of hypothalamic-pituitary-adrenal (HPA) axis suppression when patients are switched from systemic corticosteroids to inhaled corticosteroids. You did not request that the warning be deleted, only that it no longer be surrounded by a black box. We are granting your petition for the reasons given below.

We agree that prescribing physicians are much more familiar with the use of inhaled corticosteroid drugs than they were when inhaled corticosteroid drug products were first introduced. We also agree that fewer asthmatics are being treated with systemic corticosteroid drug products than at the time inhaled corticosteroid drug products were first introduced. Both of these factors indicate that a warning about the risk of HPA axis suppression when patients are switched from systemic corticosteroids to inhaled corticosteroids no longer needs to be given the same prominence. This conclusion is supported in part by our review of data generated by our Adverse Event Reporting System (AERS) in which no instances of HPA axis suppression resulting from switching from systemic corticosteroids to inhaled corticosteroids were found. Accordingly, we have determined that the black box is no longer needed on the labeling of inhaled corticosteroid drug products.

We invite labeling supplements to provide for the removal of the black box around the warning about the risk of HPA axis suppression from the labeling of inhaled corticosteroid drug products.

Sincerely yours,

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

OIP-0268

PAV 1