HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 14 2011

2011 APR 18 A 8:25

Anil K. Mandal, M.D.
665 State Road 207, Suite 102
St. Augustine, Florida 32084

Re: Docket No. FDA-2006-P-0008

Dear Dr. Mandal:

This letter responds to your "Appeal of Denial" letter dated November 8, 2010, regarding the Food and Drug Administration's (FDA's) August 3, 2010, decision to deny your original citizen petition (FDA-2006-P-0008) (Original Petition). In your Original Petition, you requested that FDA restrict the use of or withdraw from the market angiotensin converting enzyme inhibitor (ACEI) and angiotensin receptor blocker (ARB) drug therapy in certain conditions because of an association with acute renal failure.

FDA has carefully considered the information submitted in your letter, and for the reasons explained below, FDA upholds its previous decision to deny your Original Petition.

I. BACKGROUND

The Original Petition requested that FDA withdraw ACEI and ARB drug products from the market or restrict their use for the following conditions or patient populations:

(1) Diabetes mellitus with uncontrolled hyperglycemia
(2) Patients with diuretic therapy
(3) Diabetes mellitus with gastroparesis giving rise to vomiting
(4) Diabetic autonomic neuropathy with diarrhea
(5) Stable chronic renal failure in diabetic, hypertensive, or congestive heart failure patients
(6) Elderly patients
(7) Debilitated patients with tube feeding

The Original Petition claimed that the use of ACEI or ARB therapy in combination with the concomitant therapies or other risk conditions listed above increases the risk of acute renal failure. You also asserted in the Original Petition that as a practitioner, you have not seen improvement or stabilization of renal function with the use of ACEI or ARB drug therapies.

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ANS

In FDA's petition response dated August 3, 2010 (Citizen Petition Response), we denied your request to remove from the market or restrict the use of ACEI and ARB drug therapies because the net benefit of these drug products far exceeds the potential harm, even when used in the populations with the risk conditions listed above. The clinical trial data support the safety and efficacy of ACEI and ARB drug products, including use in diabetic patients. Furthermore, we determined that the current labeling for these drug products is adequate to address your concerns regarding renal dysfunction.

Your appeal of denial of the Citizen Petition Response is based on your experience as a physician treating patients and your observations of adverse events associated with ACEI and ARB therapy. You believe that ACEI and ARB drug therapies continue to be unsafe.

II. DISCUSSION

The letter you submitted states that it is an "Appeal of Denial" of your Original Petition by FDA. It appears that you intended to submit a petition for reconsideration. Our regulations state that an interested person can request reconsideration of a decision on a petition under 21 CFR 10.33. The Commissioner may grant a petition for reconsideration if the Commissioner determines the petition to be in the public interest and in the interest of justice (21 CFR 10.33(d)). In addition, the Commissioner will grant a petition for reconsideration if the Commissioner determines that all of the following apply:

(1) The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered.
(2) The petitioner's position is not frivolous and is being pursued in good faith.
(3) The petitioner has demonstrated sound public policy grounds supporting reconsideration.
(4) Reconsideration is not outweighed by public health or other public interests.

In addition, a petition for reconsideration may not be based on information and views not contained in the administrative record on which the decision was made (21 CFR 10.33(e)). It is important to note that under 21 CFR 10.33(b), a petition for reconsideration must be submitted within 30 days after the date of the decision involved. The Commissioner may, for good cause, permit a petition to be filed more than 30 days after the date of the decision involved.

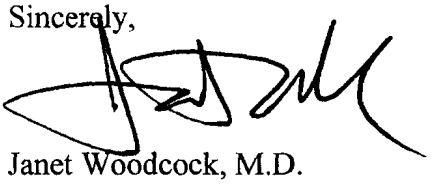
You letter does not satisfy the requirements of a petition for reconsideration, particularly the requirement that it be submitted within 30 days after the date of the decision involved, and you have not demonstrated good cause to permit the submission of a petition for reconsideration more than 30 days after the date of the decision involved. We should note, however, that even if we had reviewed your letter and your Original Petition on the merits, we would not have changed our decision in the Citizen Petition Response; the reasons for that conclusion are explained in the Citizen Petition Response and your letter

does not provided a basis for a different conclusion. We conclude that the relevant information and views in the administrative record were adequately considered when we reviewed and denied your Original Petition. We also conclude that the data and information submitted in support of the Original Petition and your appeal of denial letter are not sufficiently persuasive to cause us to modify or overrule the Citizen Petition Response.

III. CONCLUSION

For the reasons described above, the Agency denies the letter requesting an appeal of FDA's decision to deny the Original Petition.

Sincerely,



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