DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 19 2010

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Sidney M. Wolfe, M.D.
Public Citizen
1600 20th Street, N.W.
Washington, D.C. 20009

Re: Docket No. FDA-2006-P-0270/PRC

Dear Dr. Wolfe:

This letter responds to your Petition for Reconsideration submitted on August 6, 2009, in which you ask the Food and Drug Administration (FDA or Agency) to reconsider our decision of July 7, 2009,[1] denying your Citizen Petition (Docket No. FDA-2006-P-0270). The Citizen Petition requested that FDA withdraw propoxyphene-containing drug products from the U.S. market.

As detailed in our July 7, 2009, decision, we found the evidence available at the time to be insufficient to support removing propoxyphene products from the market. However, to address potential cardiotoxity concerns, FDA required the sponsor of the new drug application product, Xanodyne, to conduct a QT study (the thorough QT, or "TQT," study) to further evaluate the effects of propoxyphene on cardiac electrophysiology.

FDA has now reviewed the results of the sponsor's preliminary pharmacokinetic study, which was conducted to determine appropriate dosing for the TQT study. The Agency has concluded that the data demonstrate a clear, dose-related effect on cardiac electrophysiology. These results, in conjunction with other postmarketing signals, including expanded epidemiological analyses, provide evidence that propoxyphene can have an adverse cardiotoxic effect at therapeutic doses.

[1] Letter from Janet Woodcock, M.D., to Sidney M. Wolfe, M.D.; Mr. Dan Suzman; Ulf Jonasson, DrPH; and Birgitta Jonasson, PhD, July 7, 2009, denying the Citizen Petition filed February 28, 2006. The Citizen Petition was originally assigned docket number 2006-P-0090. The number was changed to FDA-2006-P-0270 as a result of FDA's transition to its new docketing system (Regulations.gov) in 2008.

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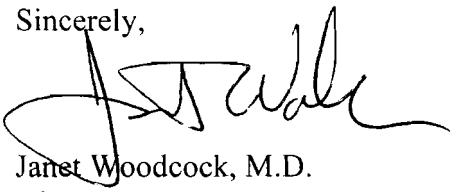
Accordingly, we have concluded that the weight of evidence has shifted and the overall balance of risk to benefit for propoxyphene is no longer favorable. Today, we announced that we are taking action to remove propoxyphene-containing drug products from the market. The basis for this determination and FDA's current regulatory position are detailed in a decision memorandum and related background materials that may be accessed at www.fda.gov.

Although the agency is taking the action that you requested in your petition, it is doing so on the basis of data and studies that were not part of your original Citizen Petition. Thus, your Petition for Reconsideration is hereby denied.

Sincerely,



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