



**DEPARTMENT OF HEALTH AND HUMAN SERVICES** **Public Health Service**  
*Food and Drug Administration*  
*Division of Freedom of Information*  
*5600 Fishers Lane, HFI-35*  
*Rockville, MD 20857*

February 3, 2010

In Response Refer to File: **2010-2**

Michael C. Barnes  
DCBA Law Policy  
2009 N 14<sup>th</sup> Street, Suite 414  
Arlington, Virginia 22201

Dear Requestor:

This is in response to your letter received by FDA on January 4, 2010 in which you requested information concerning the new safety information, as defined by Section 505-1(b)(3) of the FDAAA for a list of 9 brand-name opioid drugs and the data for each of the Opioids listed which it determined a) that the elements of REMS described in section 355-1(c-e) of the FDAAA are (1) necessary and (2) yet insufficient to mitigate the medication's risk and b) that each medication would be withdrawn from the market but for the requirement of ETASU.

FDA has not yet required a REMS for these products, and we have not yet made the findings required by FDAAA for the 9 brand-name opioid drugs that you've listed (e.g., the findings that a REMS is necessary to ensure the benefits of the drug outweigh the risks, the finding of new safety information for marketed products, or the finding that the REMS must include elements to assure safe use). Therefore, we have not identified any records responsive to your request.

Charges of \$ 23.00 Search Time will be sent in a monthly invoice. PLEASE DO NOT MAKE ANY PAYMENT UNTIL YOU RECEIVE AN INVOICE.

**If there are any problems with this response, please notify us in writing of your specific problem(s) at the above address. Please reference the above file number.**

This concludes the response for the Center for Drug Evaluation and Research. If I can be of further assistance to you, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink that reads "Roy V. Castle, Jr." with a stylized flourish at the end.

Roy V. Castle, Jr. MS, PD  
Office of Regulatory Policy  
Division of Information Disclosure Policy