



**ATTACHMENT 2**

- **Acorda Orange book Staff Letter (July 28, 2006)**
- **FDA Orange Book Staff Response Letter (Spet. 12, 2006)**



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville MD 20857

September 12, 2006

**RECEIVED**

SEP 18 2006

**ACORDA  
THERAPEUTICS**

Acorda Therapeutics  
Attn: Brian Walter, Ph.D.  
15 Skyline Drive  
Hawthorne, NY 10532

Re: Zanaflex Capsules™ (tizanidine hydrochloride)  
NDA 21-447

Dear Dr. Walter,

The Orange Book Staff received your letter dated July 28, 2006 in which you asked us to review the manner that Acorda's Zanaflex Capsules is displayed in the Orange Book. Although your proprietary name encompasses the word "capsules" it is not our policy to add the dosage form to the listed name. For this reason your product will remain listed in the Orange Book as Zanaflex.

If you have any further question please contact me at (301) 827-7376.

Sincerely,

A handwritten signature in cursive script that reads "Carrie Lemley".

Carrie Lemley  
Technical Information Specialist  
Orange Book Staff



July 28, 2006

FDA/CDER Orange Book Staff  
Office of Generic Drugs, HFD-610  
7500 Standish Place  
Rockville, MD 20855-2773

**Re: Zanaflex Capsules™ (tizanidine hydrochloride)**  
**NDA 21-447**

**GENERAL CORRESPONDENCE**

Dear Orange Book Staff,

We are writing to you to inform you that the proprietary name for Acorda Therapeutic' (Acorda) product **Zanaflex Capsules™ (tizanidine hydrochloride)** is incorrectly listed in the 26<sup>th</sup> edition of the Orange Book (2006). The orange book lists the proprietary name Zanaflex Capsules™ incorrectly as "Zanaflex" which has lead to some confusion with the tizanidine hydrochloride tablet product and unauthorized switching between tablets and capsules. The two drug products are not bioequivalent.

On April 8, 2005 Acorda submitted FDA Form 2657 to FDA/CDER Drug Registration and Listing for Zanaflex Capsules™ (tizanidine hydrochloride). This submission correctly lists the proprietary name for the drug product as Zanaflex Capsules™.

Acorda would appreciate if you could correct the listing of Zanaflex Capsules™ as soon as possible. Changes are required in the Orange Book on the following pages 367, 728, 731 and 980.

If you have any questions or comments regarding this submission, please contact me at (914) 347-4300, ext 139.

Sincerely,

A handwritten signature in cursive script that reads "Brian A. Walter".

Brian A. Walter, Ph.D.  
Senior Director Regulatory Affairs  
And Quality Assurance

Desk Copy: Dr. Russell Katz, Director, FDA, Division of Neurology Products