

DIVISION OF CARDIOVASCULAR AND RENAL PRODUCTS
MEDICAL OFFICER'S MEMORANDUM
Written Request Error

IND: 21-437-005

Name of Drug: eplerenone

Trade Name: Inspra

Formulation: tablets

Related Application: IND 51,780

Proposed Indication: hypertension

Sponsor/Monitors: Pfizer

Date of Submission: 7/31/07

Date of Memorandum: 10/19/07

Reviewer: Thomas A. Marciniak, M.D.

In reviewing the pediatric supplement for eplerenone, I noted that the last revised version of the pediatric written request, dated June 7, 2006, specified a due date for the reports of August 17, 2006. The latter date in 2006 was a typographical error: It should have been August 17, 2007, consistent with the due date specified in our letter dated October 1, 2004, regarding PREA requirements.

Thomas A. Marciniak, M.D.
Medical Team Leader

cc:

ORIG: NDA 21-437

HFD-110

HFD-110/CSO

HFD-110/TMarciniak

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this page is the manifestation of the electronic signature.**

/s/

Thomas Marciniak
10/19/2007 11:32:53 AM
MEDICAL OFFICER