CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 21-856

OTHER REVIEWS

ADRA Rev #1 of Action Package for NDA 21-856, Uloric (febuxostat) Tablets

Reviewer: Lee Ripper, HFD-102
Date received: 9/23/05
Date of review: 9/27/05; *10/13/05*
Date original NDA received: 12/15/05
UF goal date: 10/14/05

Proposed Indication: Mgmt of hyperuricemia in patients with gout
Action type: AE
RPM: Jane ~~Ware~~ Dean
Drug Classification: 1S
505(b)(1) application

Patent Info on form FDA 3542a: AC
Debarment Certification: AC
Financial Disclosure: Page 24
Safety Update: Safety rev, p. 105 - results in SU were incorporated into main body of review.
Risk Management Plan: PPI
Clinical Inspection Summary: AC
ODS/DMETS Review of Proprietary Name: AC 2/25/05
DSRCS Review of PPI: 4/7/05
DDMAC Review: AC 8/31/05
EA: CE claimed
EER: AC 8/1/05
WU Mtg: None. Reg Briefing held 8/12/05. Internal FU mtg on 8/17/05.

CMC section to Eric Duffy, 9/28/05. *Rev finalized 10/12/05.*
P/T section to Ken Hastings, electronic pkg 9/28/05. *Rev finalized 10/13/05*

1. A Pediatric Page needs to be completed and put into DFS and the Action Package.
2. No statistical review in DFS. *Finalized 10/12/05.*
3. Medical TL/Deputy Director review is pending.
4. Action letter has not been received. *Draft AE letter rec'd and comments ret'd to RPM on 10/13/05.*

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Leah Ripper
10/13/2005 05:48:48 PM
CSO