CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

021446Orig1s028

CHEMISTRY REVIEW(S)

Chemistry Review #1	**1. ONDQA** HFD-170	**2. NDA/Suppl. Number** 21-446/SE8-028
3. Name and Address of Applicant Pfizer Consumer Health Care Products Attention: Samantha McNamara, Regulatory Health PM 235 E 42nd Street, New York, NY 10017		**4. Date of Sub.** 12/20/11 **User Fee** 6/20/12
5. Name of Drug Lyrica	**6. Nonproprietary Name** Pregabalin	
7. Supplement, Prior Approval, for A new indication; management of neuropathic pain associated with spinal cord injury.		**8. Amendment(s)** NA
9. Pharmacological Category	**10. How Dispensed:** **Rx**	**11. Related Documents**: None
12. Dosage Form Capsules	**13. Potency(ies):** 25, 50, 75, 100, 150, 200, 225, & 300 mg	
13. Chemical Name and Structure: See USAN		

15. Comments:

Reference was made to the pre-sNDA correspondence dated 30 September 2011 between the DAAAP and Pfizer. Agreement was reached on submission content, cross referencing original NDA 21-446 to support the proposed indication for management of neuropathic pain associated with spinal cord injury. The sponsor has requested priority review and a waiver of pediatric studies for this new indication.

The manufacturing process and specifications for Lyrica drug product remain unchanged. There are no changes in CMC section of the labeling. Supplement - 025 is the last supplement that contained approved labeling and revised CMC.

EA review is done. The review is in DARRTS.

16. Conclusions and Recommendations: Recommend approval from CMC point of view.

17. Name: Review Chemist **Signature** **Date**

Bart Ho, Chemist

Branch Chief
James D. Vidra, Ph.D.

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/s/

BARTHOLOME C HO
06/18/2012

JAMES D VIDRA
06/18/2012