

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-908s005**

**CHEMISTRY REVIEW(S)**

CHEMIST'S REVIEW # 1		1. <u>Organization:</u> HFD-180	2. <u>NDA number:</u> 21-908
3. <u>Name and Address of Applicant (City &amp; State):</u> Sucampo Pharmaceuticals, Inc. 4733 Bethesda Avenue, Suite 450 Bethesda, MD 20814		4. <u>AF Number:</u>	5. <u>Supplement(s)</u>
6. <u>Name of Drug:</u> Amitiza®	7. <u>Nonproprietary Name:</u> Lubiprostone	Numbers SE1-005	Dates June 29, 2007
8. <u>Supplement Provides for:</u> <ul style="list-style-type: none"> <li>Qualification of a 8 µg strength capsule (dosage form marketed currently is 24 µg capsule);</li> <li>New indication (irritable bowel syndrome with constipation [IBS-C]).</li> </ul>		9. <u>Amendments &amp; Other (Reports, etc.) Dates:</u> BL August 16, 2007 BM August 31, 2007 MR September 17, 2007 BM September 19, 2007 BS October 10, 2007 MP October 24, 2007 SU November 21, 2007 BS February 7, 2008 BZ March 12, 2008 BZ March 24, 2008 BL April 10, 2008 April 14, 2008 (electronic)	
10. <u>Pharmacological Category:</u> Treatment of constipation and bowel preparation	11. <u>How Dispensed:</u> RX <input checked="" type="checkbox"/> OTC	12. <u>Related IND/NDA/DMF(s):</u> DMF (b)(4) (lubiprostone 24 and 8 mcg capsules) Adequate DMF (b)(4) Adequate	
13. <u>Dosage Form:</u> Capsule	14. <u>Potency:</u> 24 µg		
15. <u>Chemical Name and Structure:</u> Prostan-1-oic acid, 16,16-difluoro-11-hydroxy-9,15-dioxo-, (11α)-.  Molecular formula: C <sub>20</sub> H <sub>32</sub> F <sub>2</sub> O <sub>5</sub> . Molecular mass: 390.46. CAS no. 136790-76-6  For molecular structure, see Review Notes below.		16. Records and Reports:  Current Yes ___ No  Reviewed Yes ___ No	
17. <u>Comments:</u> All the amendments listed above in 9. were evaluated. The information most relevant to CMC is provided in only the original submission, the labeling amendments dated August 16, 2007 and April 14, 2008, and the amendments dated March 12, 24, and April 10, 2008.  CC: NDA 21-908 HFD-180/Div File/NDA 21-908 ONDQA/DPE/VIII/TBouie ONDQA/DPE/VIII/RFrankewich R/D init: HPatel			
18. <u>Conclusions and Recommendations:</u> From a CMC standpoint, this supplement may be approved.			
19. <u>Reviewer</u>			
Name: Raymond P. Frankewich, Ph.D.	Signature	Date Completed: April 18, 2008	

**44 Page(s) of Draft Labeling have been Withheld in Full immediately following this page as B4 (CCI/TS)**

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/s/

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Ray Frankewich  
4/22/2008 02:21:25 PM  
CHEMIST

Hasmukh Patel  
4/22/2008 02:23:59 PM  
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