

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**206088Orig1s000**

**ENVIRONMENTAL ASSESSMENT**

<b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b> <b>PUBLIC HEALTH SERVICE</b> <b>FOOD AND DRUG ADMINISTRATION</b>			<b>EAS REVIEW REQUEST</b>	
<b>TO:</b> <b>ENVIRONMENTAL ASSESSMENT STAFF</b>  <b>E-mail to: CDER OPS IO EA</b> <b>Paper mail to: WO Bldg 51, Room 4193</b>			<b>FROM (Name, Title, Office/Division):</b> Kerri-Ann Jennings, PM, ONDQA/X62919 c/o Requestor- CMC Lead, Shulin Ding  Primary CMC Reviewer- Caroline Strasinger	
<b>REQUEST DATE</b> 05 NOV 2013	<b>IND #</b>	<b>NDA / ANDA (Supplement) #</b> NDA 206088	<b>TYPE OF DOCUMENT</b> Electronic	<b>DATE OF DOCUMENT</b> 23 SEPT 2013
<b>NAME OF DRUG</b> apremilast		<b>PRIORITY CONSIDERATION</b>  NME	<b>PDUFA DATE</b> 23 SEPT 2014	<b>DESIRED COMPLETION DATE</b> 28 FEB 2014
<b>NAME OF APPLICANT OR SPONSOR:</b> Celgene				
<b>GENERAL PROVISIONS IN APPLICATION</b>				
<input checked="" type="checkbox"/> ENVIRONMENTAL ASSESSMENT <input type="checkbox"/> ENVIRONMENTAL IMPACT STATEMENT <input checked="" type="checkbox"/> CLAIM OF CATEGORICAL EXCLUSION <input type="checkbox"/> OTHER				
<b>EDR Link:</b> <a href="\\CDSESUB1\EVSPROD\NDA206088\206088.enx">\\CDSESUB1\EVSPROD\NDA206088\206088.enx</a>				
<b>eCTD Sequence Number:</b> 0000				
<b>COMMENTS / SPECIAL INSTRUCTIONS:</b>  Please evaluate the applicant's claim for categorical exclusion from preparation of an Environmental Assessment for NDA 206088.  Please note that NDA 206088 is submitted to Division of Dermatology and Dental Products for the indication of psoriasis. The same product is also the subject of NDA 205437 submitted to Division of Pulmonary, Allergy, and Rheumatology Products. NDA 205437 was received by CDER on March 21, 2013. Its PDUFA date is March 21, 2014.				
<b>SIGNATURE OF REQUESTER:</b>		<b>DOCUMENTS FOR REVIEW DELIVERED BY (Check one):</b>  <input type="checkbox"/> EDR <input type="checkbox"/> E-MAIL <input type="checkbox"/> MAIL <input type="checkbox"/> HAND		

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

/s/  
-----

KERRI-ANN JENNINGS  
11/07/2013