

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**204063Orig1s000**

**CHEMISTRY REVIEW(S)**

**MEMORANDUM**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

**DATE:** 20 MAR 2013  
**FROM:** David J. Claffey, PhD  
**SUBJECT:** Approval recommendation for NDA 204063

On 20 MAR 2013 CDER Office of Compliance issued and overall acceptable recommendation for the manufacturing sites associated with this application. An approval recommendation for this application can now be made from a CMC perspective.

# ATTACHMENT

## OC Recommendation

### FDA CDER EES ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

<b>Application:</b>	NDA 204063/000	<b>Sponsor:</b>	BIOGEN IDEC INC
<b>Org. Code:</b>	120		14 CAMBRIDGE CENTER
<b>Priority:</b>	1		CAMBRIDGE, MA 02142
<b>Stamp Date:</b>	27-FEB-2012	<b>Brand Name:</b>	dimethyl fumarate
<b>PDUFA Date:</b>	27-MAR-2013	<b>Estab. Name:</b>	
<b>Action Goal:</b>		<b>Generic Name:</b>	dimethyl fumarate
<b>District Goal:</b>	26-JAN-2013	<b>Product Number; Dosage Form; Ingredient; Strengths</b>	
			001; CAPSULE, DELAYED ACTION; DIMETHYL FUMARATE; 120MG 002; CAPSULE, DELAYED ACTION; DIMETHYL FUMARATE; 240MG
<b>FDA Contacts:</b>	T. BOUIE	Project Manager	3017961649
	D. CLAFFEY	Review Chemist	3017961343
	M. HEIMANN	Team Leader	3017961678

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<b>Overall Recommendation:</b>	ACCEPTABLE	on 20-MAR-2013	by D. SMITH	(HFD-323)	3017965321
	PENDING	on 08-MAR-2012	by EES_PROD		
	PENDING	on 08-MAR-2012	by EES_PROD		

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<b>Establishment:</b>	(b) (4)	
<b>DMF No:</b>		<b>AADA:</b>
<b>Responsibilities:</b>		
<b>Profile:</b>		<b>OAI Status:</b> NONE
<b>Last Milestone:</b>	OC RECOMMENDATION	
<b>Milestone Date:</b>	20-MAR-2012	
<b>Decision:</b>	ACCEPTABLE	
<b>Reason:</b>	DISTRICT RECOMMENDATION	

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FDA CDER EES  
ESTABLISHMENT EVALUATION REQUEST  
SUMMARY REPORT

<b>Establishment:</b>	(b) (4)	
<b>DMF No:</b>		<b>AADA:</b>
<b>Responsibilities:</b>		
<b>Profile:</b>		<b>OAI Status:</b> NONE
<b>Last Milestone:</b>	OC RECOMMENDATION	
<b>Milestone Date:</b>	11-MAR-2012	
<b>Decision:</b>	ACCEPTABLE	
<b>Reason:</b>	BASED ON PROFILE	
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<b>Establishment:</b>	(b) (4)	
<b>DMF No:</b>		
<b>Responsibilities:</b>		
<b>Profile:</b>		NONE
<b>Last Milestone:</b>	OC RECOMMENDATION	
<b>Milestone Date:</b>	11-MAR-2012	
<b>Decision:</b>	ACCEPTABLE	
<b>Reason:</b>	BASED ON PROFILE	
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<b>Establishment:</b>	(b) (4)	
<b>DMF No:</b>		<b>AADA:</b>
<b>Responsibilities:</b>		
<b>Profile:</b>		<b>OAI Status:</b> NONE
<b>Last Milestone:</b>	OC RECOMMENDATION	
<b>Milestone Date:</b>	11-MAR-2012	
<b>Decision:</b>	ACCEPTABLE	
<b>Reason:</b>	BASED ON PROFILE	
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**FDA CDER EES  
ESTABLISHMENT EVALUATION REQUEST  
SUMMARY REPORT**

Establishment: (b) (4)

DMF No: AADA:

Responsibilities: Profile: OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 11-MAR-2012

Decision: ACCEPTABLE

Reason: BASED ON PROFILE

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Establishment: (b) (4)

DMF No: AADA:

Responsibilities: Profile: OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 18-MAR-2013

Decision: ACCEPTABLE

Reason: DISTRICT RECOMMENDATION

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Establishment: (b) (4)

DMF No: AADA:

Responsibilities: Profile: OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 20-MAR-2013

Decision: ACCEPTABLE

Reason: DISTRICT RECOMMENDATION

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