CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202155Orig1s000

CHEMISTRY REVIEW(S)

ONDQA Division Director's Memo
NDA 202570, ELIQUIS (Apixaban) Tablets, 2.5 and 5.0 mg
Date: 22-JUN-2012

The NDA for ELIQUIS (Apixaban) film coated tablets (Bristol Myers Squibb) was submitted via a 501(b)(1) NDA application (standard review clock). All consults to this review have been completed.

The drug substance is adequately characterized and controlled; including Ames positive starting materials, impurities, and one intermediate.

The drug product immediate release, film coated tablets (2.5 mg [yellow debossed with "893'] and 5.0 mg [pink debossed with "894"]) are packaged for commercial distribution in HDPE bottles of 60 or 180 count as well as a 14 count blister package (5.0 mg) for physician samples.

An expiry period of 36 months for the commercial packages when stored at USP controlled room temperature is approved. For the finished tablets in the bulk container, and expiry of 12 months at ICH intermediate condition is also approved.

This NDA is recommended for approval from a Chemistry, Manufacturing and Controls standpoint.

Respecfully submitted,

Richard (Rik) Lostritto, Acting Deputy Office Director, ONDQA

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

/s/

RICHARD T LOSTRITTO
06/22/2012

MEMORANDUM

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

DATE: May 18, 2012

TO: File

THROUGH: Ramesh K. Sood, Ph.D., Branch Chief, ONDQA

FROM: Charles F. Jewell Jr, Ph.D., Sr. Regulatory Review Chemist, ONDQA

SUBJECT: Final Chemistry, Manufacturing and Controls (CMC) Approval Recommendation for NDA 202-155 (Apixaban)

On 28 February 2012 the CMC review for the NDA 202-155 (Apixaban) was filed indicating the adequacy of the application from the CMC perspective, pending a decision from the Office of Compliance on GMP inspection results of the establishments involved in the manufacturing process of apixaban drug substance and drug product.

This memo is to confirm the overall acceptable rating based on the GMP inspection results of all the pertinent sites, see the detailed report below.

This confirms that NDA 202-155 (Apixaban) is approved from the CMC perspective.

Final Establishment Evaluation Report

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Application:	NDA 202155/000	**Action Goal:**	
Stamp Date:	28-SEP-2011	**District Goal:**	28-JAN-2012
Regulatory:	28-MAR-2012		
Applicant:	BRISTOL MYERS SQUIBB	**Brand Name:**	ELIQUIS
	4000	**Estab. Name:**	
	PRINCETON, NJ 085434000	**Generic Name:**	APIXABAN
Priority:	1	**Product Number; Dosage Form; Ingredient; Strengths**	
Org. Code:	110	001; TABLET; APIXABAN; 2.5GM 002; TABLET; APIXABAN; 5MG	

Application Comment: THIS IS A QUALITY BY DESIGN APPLICATION. CONTACT ONDQA FOR PARTICIPATION ON INSPECTIONS. (on 03-OCT-2011 by D. HENRY () 3017964227)

A FORMAL RISK ASSESSMENT WAS CONDUCTED AND [redacted] (b) (4)

FDA Contacts:			
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	K. SRINIVASACHAR	Team Leader	3017961760

Overall Recommendation:	ACCEPTABLE	on 27-MAR-2012	by D. SMITH	(HFD-323)	3017969643
	PENDING	on 04-OCT-2011	by EES_PROD		
	PENDING	on 04-OCT-2011	by EES_PROD		

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