CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 202155/ S-13

Trade Name: **ELIQUIS**

Generic Name: Apixaban

Sponsor: Bristol Myers Squibb

Approval Date: 05/03/2016

Indications: ELIQUIS is a factor Xa inhibitor indicated:

- to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.
- for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery.
- for the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy.

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202155/S-013

APPROVAL LETTER

Bristol-Myers Squibb Company
Attention: Diptee Gajjar, B.Pharm, Ph.D.
Director, Global Regulatory Lead, Global Regulatory & Safety Sciences
P.O.Box 4000
Princeton, NJ 08543-4000

Dear Dr. Gajjar:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 30, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Eliquis (apixaban) 2.5 mg and 5 mg Tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides to add Bristol-Myers Squibb's facility in Humacao, Puerto Rico as a Packaging Site for apixaban Tablets.

We have completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Maryam Changi, Regulatory Business Process Manager, at (240) 402-2725.

Sincerely,

Wendy I. Wilson -S

Digitally signed by Wendy I. Wilson -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300396790, cn=Wendy I. Wilson -S
Date: 2016.05.03 09:29:27 -04'00'

Wendy Wilson-Lee, Ph.D.
Branch Chief, Branch 1 (Acting)
Division of New Drug Product 1
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

CENTER FOR DRUG EVALUATION AND RESEARCH

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CHEMISTRY REVIEW(S)

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