



Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

Our STN: BL 125392/0

Ethicon Inc
Attention: Ms. Jessica Chung
G-106-10, P.O. Box 151
Route 22 West
Somerville, NJ 08876-0151

Dear Ms. Chung:

We have received your October 5, 2012 resubmission to your biologics license application for Fibrin Sealant Patch on October 9, 2012.

The resubmission contains a revised draft Prescribing Information and Package Label that you submitted in response to our September 28, 2012 complete response letter.

We consider this a complete, class 1 response to our action letter. Therefore, the user fee goal date is December 9, 2012.

If you have any questions, please contact the Regulatory Project Manager, Tracy Tilghman, at (301) 827-9427.

Sincerely yours,

Iliana Valencia, M.S.
Chief, Regulatory Project
Management Branch
Division of Blood Applications
Office of Blood Research and Review
Center for Biologics
Evaluation and Research