DUPONT™ TYVEK® TRANSITION PROJECT
Japan Regulatory Situation

The following official document was reviewed during a three party consultative meeting on September 19th 2012 at JFMDA (Japan Federation of Medical Device Association) office. The three party consultative meeting consisted of MHLW (Ministry of Health, Labor and Welfare), PMDA (Pharmaceutical and Medical Device Agency), ARCB (Association of Registered Certification Bodies under PAL) and JFMDA. This document was reviewed and there were no objections from any of the parties.

平成20年10月23日付け薬食機発第1023001号厚生労働省医薬食品局審査管理課医療機器審査管理室長通知「医療機器の一部変更に伴う手続について」により、医療機器の滅菌製品の包装材料の変更に関する取扱いが以下のとおり示されています。

＜別紙1「軽微変更届の範囲について」の第3項「原材料または構成部品欄」の3）＞
「滅菌バリデーション基準にて保証されている範囲の包装材料、厚さ又は形態の変更」
（事例）

① バリデーションで担保されている範囲の滅菌製品の包装材料の材質及び形態の変更
（例）
－包装材料をポリエチレン単層フィルムから、ポリエステルとポリエチレンの2層フィルムへの変更
－滅菌包装を一重包装から二重包装へ変更

※今回のタイベックの供給の新ラインへの変更もこの通知に従い、各製造販売業者が薬事手続きを行うことになります。その際、該当する品目の承認書及び認証書の記述内容に応じて、必要な薬事手続き（軽微変更届又は手続き不要）を行うことに留意して下さい。

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ENGLISH TRANSLATION:

The procedure of reporting partial changes made to medical devices is documented in the PFSB/ELD/OMDE (Yakushokuki) Notification No. 1023001 as published on October 23rd, 2008 by the Director of the Medical Devices Evaluation Office, within the Evaluation and Licensing Division of the Pharmaceutical and Food Safety Bureau at the Ministry of Health, Labor and Welfare. The notification of changes to packaging materials for medical devices is specified as follows:

Attachment 1 specifies reportable changes to be covered in a minor change notification

Section 3 covers raw materials or components, which includes in its part 3:
"Changes to packaging materials, thickness, or type of packaging within the scope for which validation is ensured by the standard of sterilization"

Examples:

- Change of packaging material from single-layer polyethylene film to double-layer polyester/polyethylene film
- Change of sterile packing from single packing to double packing

Note for Manufacturers: Regarding the upcomingchange of Tyvek® supply to its new line of products, each manufacturer/distributor will undertake the pharmaceutical regulatory procedures in accordance with the above notification, and should be aware that the necessary pharmaceutical regulatory procedures (notification of a minor change or no procedure needed) will be done according to the respective certificate of approval.

What should Manufacturers do?

Based on the guidance above, it is recommended that manufacturers marketing devices in Japan, contact their Japanese subsidiaries holding the marketing authorization or their designated marketing authorization holder, that they review the guidance document PFSB/ELD/OMDE (Yakushokuki) Notification No. 1023001 as well as their respective registration forms for their devices to decide on the appropriate actions to take.

In case of further comments or questions, please contact Ichiro Ikeda, Director AP Regional Regulatory Affairs, +81 35521 8474, ichiro.ikeda@dupont.com