



NEWS

Astellas Recall Caused by Excess API

The European Medicines Agency (EMA) agreed to the immediate approval of a recall of Japanese drug maker Astellas Pharma's 0.5-mg prolonged release Advagraf capsules because more of the API tacrolimus was released from the capsules than is standard. Astellas recalled 12 batches from pharmacies and wholesalers across the EU, but mostly from the U.K. and Romania. The defect is unlikely to have caused safety issues but was carried out as a precautionary measure because it could have created slightly higher levels of tacrolimus in patients' blood that had taken the capsules.

The company found that an average of 70% of the capsules' tacrolimus was released during the first 1.5 hours of dissolution testing, whereas the specified range is 48% to 68%. The problem was discovered during routine testing by Astellas, the marketing-authorization holder, according to an EMA announcement. The recall shouldn't affect the overall supply of Advagraf but only the batches that came from one parent batch of the drug. Advagraf is used to prevent organ rejection in adults who have had a kidney or liver transplant or to treat organ rejection when other medicines have not worked.

Novartis to Cut 2,000 Swiss and U.S. Jobs

Swiss pharmaceutical giant Novartis AG will cut 1,100 jobs in Switzerland and 900 in the U.S. to offset the effect of drug price reductions driven by government austerity measures. The Basel-based company will close a plant in Nyon, Switzerland, that makes over-the-counter drugs, and chemical sites in Basel and Torre, Italy, and will transfer production to other locations or to third parties. The company will add approximately 700 new positions in low-cost countries such as India and China.

The cuts comprise 1 percent of Novartis's workforce and will be implemented over three to five years, according to a statement from the company. Some research will be moved from Switzerland to the U.S., and cutbacks will be made in technical research and



development, data management, clinical trial monitoring, drug safety and regulatory affairs. Approximately 270 preclinical safety profiling and siRNA research positions in Basel, Switzerland, will be moved to the company's Cambridge, Mass., site, according to Bloomberg News.

SAFC Launches New Cell Line for Biopharmaceutical Production

SAFC, Sigma-Aldrich's custom manufacturing and services business unit, has introduced its first commercially available product line, CHOZN® GS-/- Zinc Finger Nuclease (ZFN)-modified Chinese Hamster Ovary (CHO) cell line for the production of biopharmaceuticals. The new cell line is a glutamine synthetase (GS) knockout CHO cell line and shortens bioproduction times in early development, according to the Pharmaceutical Business Review. CHOZN® GS-/- has been developed using SAFC's proprietary CompoZr® ZFN technology that inactivates the glutamine synthetase gene, making the cells dependent on L-glutamine.

Development timelines for biopharmaceuticals can be shortened with this product, as the cells do not require MSX (or L-Methionine-D, L-sulfoximine) selection for production clone development. "Knocking out" the GS gene that produces this enzyme means the addition of this MSX inhibitor is no longer required for r-protein clone selection, which provides enhanced supply chain security, decreasing development time for identification of producing clones, and enabling customers to file Investigational New Drug (IND) applications sooner. The parental cell line is cGMP banked using Animal Component Free (ACF), Chemically Defined (CD) media and has extensive viral testing, along with a traceable history.