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with a password and user name to activate the digital certificate.

While FDA does not mandate particular technologies, agency acceptance of SAFE credentials would be a major milestone.

An FDA spokesman said that the agency is continuing to provide regulatory input on the SAFE process and implementation, in alignment with FDA's Prescription Drug User Fee Act (PDUFA) III electronic signature goal and the overall PDUFA objective to increase the number electronic submissions. The FDA is currently working with the National Cancer Institute to implement a SAFE pilot.

-Doug McCormick

API MANUFACTURING

Production Process Increases Productivity

The Texas A&M University-Kingsville (Kingsville, TX, www.tamuk.edu) Chemistry Department has patented a one-step chemical process for the production of acetaminophen that could replace the typical 4- or 5-step process.

In the new process, large amounts of solvents are replaced by a small drop of surfactant. The foam action increases the reaction's surface area and speeds the process. Because solvents aren't needed, all atoms used in the reaction vessel will become part

of the product. Typically, solvents must be removed and disposed of after synthesis.

According to Texas A&M Chemistry Professor Apurba Bhattacharya, "Because it doesn't require a solvent, it's more economically attractive. You don't have to worry about solvent, separation and purification, or disposal expenses," he says. To be more environmentally friendly, the process also is salt- and waste-free.

-Kaylynn Chiarello

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taste and the environmental issues produced by the older processes.

The pharmaceutical industry currently uses supercritical CO₂ chiefly to control the powder/particle size of

products during synthesis. Holmes hopes to extend the technique so that it can be used in the final processing, integrating front- and back-end manufacturing methods.

-George Koroneos