

Amphastar Prepares to Use E-Pedigrees

Initially, the California drugmaker will shun RFID tags for most of its products, opting for low-cost 2-D serialized bar-code labels.

By Beth Bacheldor

July 11, 2006—California's electronic pedigree legislation is set to take effect on Jan. 1, 2007. In an effort to prepare for this legislation, [Amphastar Pharmaceuticals](#) is implementing new e-pedigree software and working with its distribution partners so it can provide the proper documentation to track more accurately the drugs it manufactures as they traverse the supply chain.

Amphastar, headquarter in Rancho Cucamonga, Calif., 43 miles east of Los Angeles, manufactures and sells generic and proprietary injectable and inhalable medications, including Amphadase and Epinephrine Mist. Like other California drug makers and distributors, Amphastar will have to begin including e-pedigrees with every shipment of drugs it sends out, starting January 2007. E-pedigrees are secure files that store data about each move a product makes through the supply chain. Created via RFID or similar technologies, the files can help reduce the counterfeiting of drugs and other products.

Several other states are considering, or have already passed, similar laws. Florida, for example, has passed a bill that went into effect July 1, requiring all companies selling drugs in the state to provide an electronic pedigree. In California, the pedigree must start with the manufacturer.

California's position on drug pedigrees stems, in part, from a 2004 case involving counterfeit Viagra. The high-profile case prompted an aggressive RFID plan from Viagra's maker, [Pfizer](#), which is now using the technology to thwart Viagra counterfeiters (see [Pfizer Using RFID to Fight Fake Viagra](#)).

Amphastar's new e-pedigree system consists of software and shipping documents. While the company will use two-dimensional bar codes with unique serial numbers to identify its products and verify that they originated from Amphastar, it is also considering adding RFID technology. RFID tags would provide a more effective trail of authenticity, because the unique serial number stored on each tag can be read automatically and matched against the serial number in the e-pedigree document, thereby eliminating the manual scanning needed with bar codes.

After Amphastar takes its e-pedigree system live to coincide with California's January deadline, the company says it will likely continue using 2-D bar-coded labels for at least some of its product offerings, rather than RFID tags. That's because the company believes RFID tags are prohibitively expensive to use with low-priced low-margin generic drugs.

According to Amphastar, not all of its distributors may be ready to receive e-pedigrees because they may not have implemented the necessary technology to do so. In such cases, Amphastar will fax or e-mail pedigrees to those distributors unable to electronically accept the pedigree files.

Company executives declined to provide further details, citing an [SEC](#)-enforced quiet period resulting from its

February 2005 filing for an initial public offering with the SEC. The IPO process is ongoing, and the underwriters on the deal will be Lehman Brothers, UBS Investment Bank and Deutsche Bank Securities. The company has also filed to list its stock on the NASDAQ exchange under ticker symbol AMPR.

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