



**FIGURE 4.2**

Two-dimensional barcode. (From Online Barcode Generator, TEC-IT, <http://barcode.tec-it.com/barcode-generator.aspx>. With permission.)

product labels contain at a minimum the National Drug Code (NDC) number (21 CFR 201.25).<sup>4</sup> Not surprisingly, the FDA chose 2D barcodes over the use of radio frequency identification (RFID) tags (Figure 4.2). I was told by an anonymous FDA representative that to store the amount of data required, an active RFID tag would have to be used. Active RFID tags cost \$15 to \$100 each. Misreads can also be an issue when the battery-powered active RFID tags lose power.<sup>5</sup>

## **Product Tracing**

The FDA is requiring manufacturers, wholesale distributors, repackagers, and pharmacies in the drug supply chain to provide information about a drug and who handled it each time it is sold in the U.S. market.<sup>6</sup> So the information about a drug should be defined as the primary suppliers of compounds, fine chemicals, and inert ingredients. This implies that suppliers such as the Professional Compounding Centers of America (PCCA) must initiate the pedigree so that its pharmacies can comply with this requirement. Paper pedigrees already exist for certain drugs, as PCCA is doing to meet the Florida pedigree law standards. Will the new requirements be different, or more of the same?

What is yet to be determined is whether the information about a drug includes the sources of packaging material. This is extremely important, as it relates to tamper-resistant and tamper-evident packaging. In addition, the “who handled it each time it is sold” requirement misses a key point. A pharmaceutical drug product can be handled by a wholesale distributor and a transportation carrier without selling the drug product. Whether the drug product is sold “FOB Origin” or “FOB Destination,” there may be a physical change in handing of the drug product without change in ownership. (FOB means freight on board, or in layperson’s terms, who pays the freight.) If the purpose is to trace a product to prevent product substitution or product adulteration, the wording of this requirement leaves out a key