

Pharmaceutical industry thrives in free trade zones

Although the 1995 Uruguay round of GATT negotiations agreed to eventually eliminate tariffs on most finished pharmaceutical products, drug manufacturers continue to flock to Foreign Trade Zones.

While certain customs advantages may be lost due to GATT, new opportunities are developing which suggest that pharmaceutical manufacturers will still utilize FTZ's. In many cases, however, they'll use them to achieve different goals.

At last count, approximately 40 pharmaceutical manufacturers, from Abbott Laboratories to Bristol-Myers Squibb to Merck & Co., are thriving in the FTZ environment, though many are adapting their business strategies to keep pace with recent legislative initiatives.

"Bristol-Myers was the first to recognize the competitive advantages to be gained from manufacturing drugs in FTZ", says attorney Marshall Miller, principal of Kansas City, Mo.-based Miller & Co. Mr. Miller helped Bristol-Myers structure that agreement, just as he's helped almost all of the other pharmaceutical giants gain FTZ status. He says the GATT accords eliminate certain advantages that first caused the pharmaceutical manufacturers to use FTZ's. However, new rules recently handed down by the Food and Drug Administration pave the way for the manufacture of drugs for export, many of which are not yet currently permitted for sale or use in the U.S.

Mr. Miller is one of the true authorities about Foreign Trade

Zones.

Even with GATT, pharmaceutical manufacturers and the makers of certain medical devices will still produce their goods in an FTZ, though the emphasis is expected to shift to products that are banned in the U.S.

This constitutes a win-win situation. The drug makers can still participate in the export market and are positioned to quickly initiate U.S. distribution once a banned product is approved for domestic sale. Meanwhile, the FDA, with its rigorous controls and oversight, appears more comfortable in approving drugs produced in the U.S. Thus, domestic manufacturers will have a leg up on overseas competition when, and if, the drugs are approved in the U.S.

Mr. Miller says it's generally assumed FTZ's are used to manufacture new products, often meaning new facilities are needed. But that's not always the situation. "Most applications," he says "are for existing things that have been around." A case in point is Sony's Dothan, Alabama audio and video tape manufacturing facility, the largest such facility in the world. Built in 1977, the plant never filed for FTZ status until recently, when it needed to find a way to compete more effectively with tape being produced in the Far East.

U.S. Foreign Trade Zones are found in 48 states and Puerto Rico. Another trend that's becoming more apparent in the FTZ orbit is the number of huge industrial parks filing for FTZ status. The major advantage for companies using industrial park FTZs is that there is no need to obtain approval

from the Foreign Trade Zones Board for warehousing and distribution operations, since the industrial park already carries that status.

Thus a company can move into an existing FTZ and immediately commence its business activities. And, if additional manufacturing authority is required, it can be quickly secured by a "fast track" process for manufacturing in a general purpose zone.

What this all means is that companies who once would have opted for attaining subzone status are now foregoing that route, instead moving to an industrial park with general purpose zone status. Normally, sub zone approval takes at least a year; the fast track approach, however, cuts the process to approximately 60 days.

Mr. Miller suggests another advantage companies gain from operating in a FTZ is an intensive exposure to the latest in U.S. Customs regulations. And that's particularly important, given the sweeping rules changes Customs is currently implementing.

"Everybody that operates in a zone already knows what all the rules are," he says, suggesting that companies without FTZ exposure often have to spend significant money and time to insure that their company is in compliance with the latest edicts from Customs. That becomes a moot point for FTZ companies, already up to speed with the latest rules, covering everything from invoicing to record keeping. "So many of the latest rules are completely new to so many companies," Mr. Miller notes.