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Indian Firm First to Gain FDA Approval for Pharma Formulation IntermediateBy **Alex Scott**

Malhotra: PFI approach would free up assets.

The U.S. FDA has for the first time approved a drug master file (DMF) and production of a finished generic drug manufactured using a pharmaceutical formulation intermediate (PFI). A PFI is comprised of active pharma ingredients (API) and excipients that are ready to be pressed into a tablet. Usually the DMF would relate only to the API. The API could then be added to excipients in a subsequent formulation step. The PFI approval relates to the sale of generic tablets of metformin hydrochloride, a treatment for type 2 diabetes by pharma formulation company Granules India (Hyderabad, India).

Experts say the new formulation-focused model could have a significant impact on the sector by providing pharma companies with the option of outsourcing formulation and active ingredient steps in one move. FDA approved Granules India's PFI in 11 months. The drug is based on a "ready to compress" mix of APIs and excipients that can be directly fed to a hopper for production of the tablets, Granules India says.

The concept is based on the use of economies of scale, and supply chain management of APIs and excipients, Granules India says. It is similar to the bulk drug intermediates model, in which drug manufacturers undertake the final synthesis steps using intermediates manufactured by contractors, the company says. Granules India claims PFI enhances productivity, avoids granulation bottlenecks, and cuts the need for regulatory compliance, and so would be less costly for pharma companies.

"It is a viable option," says Girish Malhotra, president of pharma consulting firm EPCOT International (Pepper Pike, OH). "Granules India's success will lead to many such operations, and this is big news. The system could be very attractive to big pharma as it would improve cash flow and free up assets," Malhotra says.

"Several APIs are being sold these days as plain commodities, there is hardly any profit margins in this segment," says C. Krishna Prasad, managing director, Granules India. "Hence, we decided to focus on PFIs where, because of the product's added value, profit margins are attractive in the international markets."

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