FDA Approves Morning Sickness Drug

U.S. health regulators have approved a drug to treat morning sickness that was withdrawn from the market 30 years ago amid claims, since debunked, that it caused birth defects.

The drug, Diclegis, made by Duchesnay Inc, a private Canadian company, is a generic version of a product that was initially approved in the United States under the name Bendectin in 1956. It was withdrawn in 1983 following a slew of lawsuits from mothers claiming their children had been harmed by it.

The U.S. Food and Drug Administration did not prompt Bendectin's manufacturer, Merrell Dow, to withdraw the product, and in fact the agency confirmed, in response to citizen petitions, that it had not been withdrawn because it was ineffective or posed a danger. It was withdrawn simply because the company could not afford to defend itself in court.

Like Bendectin, Diclegis consists of two main ingredients: doxylamine succinate, which is contained in several over-the-counter antihistamines; and pyroxidine hydrochloride, also known as vitamin B6. Diclectin comes in the form of a single pill and will be available only with a prescription.

Bringing the drug back to the market represents a bold move for the FDA, whose defining decision not to approve thalidomide, a sedative that was launched in Europe in 1957 and widely used to treat morning sickness before its link with birth defects was discovered, solidified the agency's legitimacy and reputation as a safety watchdog.

Morning sickness affects a large portion of pregnant women. In most cases it can be managed through dietary measures such as snacking throughout the day and drinking ginger ale. But in

rare cases, it is so severe that the woman requires hospitalization and treatment with intraveneous fluids.

(Additional reporting by Bill Berkrot in New York; Editing by Bernard Orr)