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Oramed submits pre-IND to FDA for exenatide

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Singapore: Oramed Pharmaceuticals, developer of oral drug delivery systems, submitted a pre-investigational new drug (pre-IND) package to the US FDA for ORMD-0901, an orally administered exenatide capsule. Oramed's pre-IND package submission follows its recently announced meeting request letter submitted to the FDA.

The submitted pre-IND package provides the FDA with information on Oramed's ORMD-0901 research conducted to-date, as well as a clinical trial outline for a proposed US clinical trial. The FDA's response to the pre-IND package will serve as a guide to the company for product development and preparation of a full IND application.