European Medicines Agency
Press office

London, 16 November 2007
Doc. Ref. EMEA/521472/2007

PRESS RELEASE
INFAI withdraws its marketing authorisation application for Gastromotal

The European Medicines Agency (EMEA) has been formally notified by INFAI, Institut für biomedizinische Analytik & NMR-Imaging GmbH, of its decision to withdraw its application for a centralised marketing authorisation for the medicinal product Gastromotal (1-^{13}C-caprylic acid).

Gastromotal was expected to be used to diagnose delayed stomach emptying in patients with stomach problems.

The application for marketing authorisation for Gastromotal was submitted to the EMEA on 9 March 2006. At the time of the withdrawal, it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that the withdrawal of Gastromotal was based on the identification of major clinical issues and on information that the CHMP considered that the data provided would not allow a conclusion to be drawn on a positive benefit-risk balance.

More information about Gastromotal and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the EMEA website shortly.

-- ENDS --

Notes:
1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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