

RepliGen Europe Limited

15 August 2012

Tomas Salmonson
CHMP Vice Chair
European Medicines Agency
7 Westferry Circus
Canary Wharf
London, E14 4HB
United Kingdom

Re: Withdrawal of MAA for SecreFlo, secretin, synthetic human, powder for solution for injection, EMA procedure number EMEA/H/C/002027

This letter is to inform you that Repligen Europe Limited has made the decision to withdraw the marketing authorisation application for SecreFlo, secretin, synthetic human, powder for solution for injection, EMA procedure number EMEA/H/C/002027 which was intended to be used for:

"use with magnetic resonance imaging (MRI) to improve pancreatic duct visualization for the detection of duct abnormalities to enhance clinical decision making in adults with known or suspected pancreatitis."

The withdrawal is based on the following reason:
Repligen Europe Limited is withdrawing the application since the major objections raised cannot be answered in the available timeframe.

We reserve the right to resubmit an application for this or other indication(s) in the future.

We agree for this letter to be included on the EMA website.

Faithfully yours,