

European Medicines Agency 30 Churchill Place London, E14 5EU United Kingdom

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Gastroenterology, Hepatology and Nutrition

ESPGHAN

European Society for Paediatric Gastroenterology, Hepatology and Nutrition Rue De-Candolle 16 1205 Genève, Switzerland www.espghan.org

Dear Madam, Sir

The European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) has consulted with their representatives and council members regarding the Paediatric Regulation drafted by EMA.

ESPGHAN is in full support of ameliorating clinical research in children and adolescents. There were no comments on the current draft.

ESPGHAN wishes to remain an involved stakeholder in the process.

Yours sincerely,

Gigi Veereman – ESPGHAN Secretary Raanan Shamir – ESPGHAN President