

From: Levi, Mark
Sent: Thursday, 19 July, 2018 09.40
To: 'barbara.rangetiner@octapharma.com'; Gorsche, Rita
Cc: 'Ammons, Stanley'
Subject: FDA question about AEs
Attachments: Labelling document .docx

Sensitivity: Confidential

Dear Dr. Rangetiner,
FDA clinical review team has identified following additional adverse events that are in relation to administration of Panzyga. These are outlined in the attached document. Please reply by noon Friday 20 July 2018 as to why these are not product-related.

Regards, Mark Levi
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