

From: Golding, Basil
Sent: Monday, May 04, 2015 4:59 PM
To: mtaylor@raretx.com
Cc: Thompson, Edward; Farshid, Mahmood
Subject: Anavip

Importance: High

Greetings,

Please clarify the PK information.

Your latest e-mail attachment states that the vials used for the PK study contained 81.86 mg of Antivipmyn. This does not agree with the PK parameters reported. Please recalculate the PK parameters based on the corrected dose used. Please submit this to us ASAP (preferably today) via e-mail and gateway.

Sincerely,

Basil Golding M.D.
Director,
Division of Research and Review,
OBRR/CBER/FDA

Phone: 240 402 8300