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The Netherlands

FGK Representative Service GmbH  
Heimeranstrasse 35  
80339 München | Germany

19 Juli 2021

**Subject: Withdrawal of Sildenafil FGK (sildenafil citrate), 50 mg oral lyophilisate EMEA/H/C/005439**

Dear Dr Enzmann,

***For the withdrawal of initial marketing authorisation application***

We would like to inform you that, at this point in time, FGK Representative Service GmbH, has taken the decision to withdraw the application for Marketing Authorisation of Sildenafil FGK, (sildenafil citrate), 50 mg, oral lyophilisate, which was intended to be used for the treatment of male erectile dysfunction.

This withdrawal is based on the fact that CHMP considers that the available data were not sufficient to conclude on a positive benefit-risk balance.

At present, there are no ongoing trials with Sildenafil FGK (sildenafil citrate).

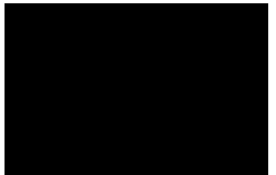
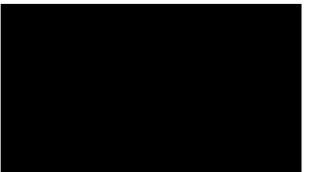
We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

We would like to take this opportunity to thank the CHMP, (Co-) Rapporteurs and the EMA for their time reviewing this application, and the guidance provided during the procedure.

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

Yours sincerely,

**FGK Representative Service GmbH**



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