

Randy Veliky @ Lexington Int

From: Randy Veliky @ Lexington Int
Sent: Monday, February 13, 2012 4:31 PM
To: si@hairmax.com
Cc: rv@hairmax.com
Subject: MDD for Androgenetic Alopecia

From: MHRA Information Centre [<mailto:info@mhra.gsi.gov.uk>]
Sent: Monday, October 05, 2009 7:51 AM
To: chap90@aol.com
Subject: RE: androgenetic alopecia question

Dear John,

Thank you for your recent enquiry to the MHRA.

Firstly, we would ask you to note that the classification rules in the USA under FDA regulations for medical devices are not the same as those in the EU and that the FDA recognise products as medical devices that are not considered to be medical devices under the EU regulations.

After investigating this matter further we can advise you that there are various sorts of alopecia and only some of these fall under the remit of the MHRA. The types that are considered to be medical conditions are those where the hair loss is unexplained (usually sudden) and often results in the loss of eyebrows and eyelashes as well. 'Androgenetic alopecia' is the medical terminology for baldness or going bald (sometimes referred to as 'pattern baldness'). Baldness or going bald in general terms is not considered to be a medical condition, therefore a product intended to 'treat' androgenetic alopecia alone (with no claims to treat any other type of alopecia) would be unlikely to be considered to be a medical device under 93/42/EEC. It is possible this is the reason why the Notified Body is unwilling to accept the claims for androgenetic alopecia in isolation as being a medical condition.

Please contact us again if you need further assistance with this, or any other queries.

Kind Regards,

Peter
on behalf of the Central Enquiry Point
Information Centre
Medicines and Healthcare products Regulatory Agency
Tel: 020 7084 2000