

Safeguarding public health

Fleuchaus & Gallo  
Patent- und Rechtsanwälte

25. Aug. 2008

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**MHRA**

Dr B Savic  
Fleuchaus & Gallo Partnerschaft  
Patent- und Rechtsanwälte  
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81479 München

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Date: 21 August 2008

**By post and e-mail**

Our ref: CAT/2008/000399

Dear Dr Savic,

**Re: Ruma Marker Test**

Thank you for your e-mail of 5 August and the information it contained.


The product contains polyethylene glycols (PEGs) in which each individual is given their own combination of PEGs. The purpose for this is to ensure that the urine sample provided by an individual is authentic and it has not been tampered with or the switching of the probes has taken place in the laboratory. It is intended to be used primarily for monitoring whether or not people in prison have taken drugs.

The Agency has now reviewed all of the information you have provided afresh. On the basis of this information the Agency takes the view that the supply or sale of this product would not be subject to the licensing and other provisions of The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (S.I. 1994/3144) or the Medicines Act 1968.

The Agency reserves the right to change its view if any other information or evidence comes to its attention which has a bearing on the status of the product, including the way in which it is promoted and presented. The Agency can give no assurance that any particular product, including products under development, will not subsequently be classified as a medicinal product. It is the responsibility of those marketing a product to ensure that it is marketed in accordance with the relevant legislation.

Finally, I enclose a copy of the Agency's Guidance Note 8 'A Guide To What is A Medicinal Product' which you may find helpful.

Yours sincerely,



Mrs Caroline Taylor  
Classifier, Medicines Borderline Section

Enc.

Cc - Mrs C Headley, Medical Devices Sector

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An executive agency of the Department of Health