



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/697285/2011
Patient Health Protection

Dear Madam

Subject: Your informal request to the European medicines agency

According to Article 1 of Directive 2001/83/EU, a medicinal product is defined as:

- (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
- (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Following review of the information you have provided, the RUMA marker system is understood to be made of a combination of different molecular weight polyethylene glycols ("PEGs"). This product is not intended for any therapeutic purposes and is to be used solely as a urine identification marker where the product is ingested by a person prior to providing a urine sample for testing. The urine containing the product may then be analysed to identify and confirm the identity of the person providing the urine sample.

Therefore, the Agency considers that this product does not fall within the definition of a medicinal product, as given in Directive 2001/83/EC so as to be eligible to access any of the procedures operated by the Agency. Please also note that medical devices do not fall within the remit of the Agency and therefore no position on whether the RUMA marker system might fall under any of the medical device provisions is given.

Please note that the EMA does not have the competence to classify products as medicinal products within the European Union merely to confirm whether they are considered to be medicinal products for the purposes of accessing one or more of the procedures for which the Agency is competent.

Should you have any other queries, please do not hesitate to contact me.

Yours sincerely,

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