2015.03.06

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Dr. G Toth
RADIOPHARMACY LABORATORIUM KFT
2 GYAR STREET
BUDAORS
HU-2040
HUNGARY

03/03/2015

Dear Dr. Toth,

GRANT / RENEWAL OF MARKETING AUTHORISATION

Our Reference:	PL 40129/0002 - 0001
Your Reference:	40129
Product:	NanoScan 500micrograms, Kit for radiopharmaceutical preparation
Type of Procedure:	Mutual Recognition
Submission Type:	Initial
Submission Category:	Abridged
EU Procedure Number (if applicable):	DK/H/01523/001

The Licensing Authority agrees to the grant or renewal of the marketing authorisation for the above submission on the basis of the data provided. This includes any replacement and amendment of the original dossier.

In line with Article 23a of Directive 2001/83/EC as amended, the Marketing Authorisation Holder should submit notification of the actual date of marketing of the product to the Competent Authority.
This notification should be provided by email to the following address: sunsetclause@mhra.gsi.gov.uk.

The formal documents are enclosed. These constitute evidence of authorisation. If you consider them to contain information that is incorrect or not in accordance with the dossier, please return immediately indicating any errors.

All Marketing Authorisations are subject to standard provisions contained in current medicines regulations full details of which are published on the MHRA website:

http://www.mhra.gov.uk/Howwereguiate/Medicines/Licensingofmedicines/Informationforlicenceapplicants/Provisionstowhichthemarketingauthorisationisgranted/index.htm

Yours sincerely,

Christopher Penny

The Medicines for Human Use (Marketing Authorisations etc.) Regulations, SI 1994/3144, as amended.

GRANT / RENEWAL OF MARKETING AUTHORISATION

Product: NanoScan 500micrograms, Kit for radiopharmaceutical preparation
Submission Type: Initial

Granted to: RADIOPHARMACY LABORATORIUM KFT
2 GYAR STREET
BUDAORS
HU-2040
HUNGARY

This Marketing Authorisation, under the above reference number is hereby granted / renewed in respect of the product named above. The Summary of Product Characteristics of the product is set out in the attached document.

The application is subject to the further provisions set out or referred to in the above Regulations.

This Marketing Authorisation, as now granted / renewed, unless previously revoked, will continue in force until the expiry date (if applicable) given below.

Grant Date: 13/02/2015

Christopher Penny
A person authorised to sign on behalf of the Secretary of State for Health

PL 40129/0002 - 0001