European Medicines Agency

Doc. Ref. EMEA/156983/2009
P/49/2009

EUROPEAN MEDICINES AGENCY DECISION

of 24 March 2009

on the refusal of a product specific waiver for melatonin (Circadin) (EMEA-000440-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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EUROPEAN MEDICINES AGENCY DECISION

of 14 March 2009

on the refusal of a product specific waiver for melatonin (Circadin) (EMEA-000440-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use as amended and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by RAD Neurim Pharmaceuticals EEC Ltd on 7 November 2008 under Article 13 of Regulation (EC) No 1901/2006 as amended,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 February 2008 in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee has given an opinion on the refusal of a product specific waiver,

(2) It is therefore appropriate to adopt a Decision refusing a waiver.

[1] OJ L 378, 27.12.2006, p.1
[2] OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

Article 1

A waiver for melatonin (Circadin), prolonged-release tablet, oral use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby refused.

Article 2

This decision is addressed to RAD Neurim Pharmaceuticals EEC Ltd, 6 Fortuna Court, Calleva Park, RG7 8UB Aldermaston, United Kingdom.

Done at London, 24 March 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDOCO/24393/2009
EMEA-000440-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE REFUSAL OF A PRODUCT-SPECIFIC WAIVER

Scope of the application

Active substance:
Melatonin

Invented name:
Circadin

Condition(s):
Primary insomnia

Pharmaceutical form(s):
Prolonged-release tablet

Route(s) of administration:
Oral use

Name/corporate name of the waiver applicant:
RAD Neurim Pharmaceuticals EEC Ltd

Information about the authorised medicinal product: see Annex I

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, RAD Neurim Pharmaceuticals EEC Ltd submitted to the EMEA on 7 November 2008 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 11 December 2008.

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Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report, to refuse the granting of a product-specific waiver for all subsets of the paediatric population for the above mentioned condition as it does not meet the grounds detailed in Article 11(1) of said Regulation.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The scientific conclusions and the grounds for refusal are set out in the summary report appended to this opinion.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex and appendix(ces).

London, 6 February 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/07/392/001-002	Circadin	2mg	Prolonged-release tablet	Oral use	PVC/PVDC blister/alu		21 tablets