European Medicines Agency

Doc. Ref. EMEA/625241/2008
P/106/2008

EUROPEAN MEDICINES AGENCY DECISION

of 28 November 2008

on the application for product specific waiver for perflubutane EMEA-000194-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)

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

EUROPEAN MEDICINES AGENCY DECISION

of 28 November 2008

on the application for product specific waiver for perflubutane EMEA-000194-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 Nycomed Danmark ApS on 3 March 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 14 November 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, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) of Regulation (EC) No 1901/2006 as amended, a negative opinion,

(2) It is therefore appropriate to adopt a Decision denying 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 perflubutane, lyophilisate for suspension for injection, intravenous 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 denied.

Article 2

This decision is addressed to Nycomed Danmark ApS, Langebjerg 1, 4000 – Roskilde, Denmark.

Done at London, 28 November 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

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

EMEA/PDCO/531843/2008
EMEA-000194-PIP01-08

NEGATIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A PRODUCT SPECIFIC WAIVER FOR (AFTER RE-EXAMINATION)

Scope of the application

Active substance:
Perflubutane

Condition(s):
Visualisation of myocardial perfusion for diagnostic purposes

Pharmaceutical form(s):
Lyophilisate for suspension for injection

Route(s) of administration:
Intravenous use

Name/corporate name of the waiver applicant:
Nycomed Danmark ApS

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Nycomed Danmark ApS submitted for agreement to the EMEA on 3 March 2008 an application for a waiver on the grounds set out in Article 11(1) of Regulation (EC) No 1901/2006 as amended for the above mentioned medicinal product.

An Opinion was adopted by the Paediatric Committee on 19 September 2008, recommending the refusal of a waiver for all subsets of the paediatric population and all the above mentioned conditions for the above mentioned product. Nycomed Danmark ApS received the Paediatric Committee Opinion on 24 September 2008.

Nycomed Danmark ApS submitted written notice including detailed grounds to the EMEA on 20 October 2008 to request a re-examination of the Opinion.

The re-examination procedure started on 21 October 2008.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for the re-examination request in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, maintains its opinion and recommends, as set out in the appended summary report, to refuse the granting of a waiver for all subsets of the paediatric population and the above mentioned condition as the condition is not meeting the grounds detailed in Article 11(1) of Regulation (EC) No 1901/2006 as amended.

The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The scientific conclusions and the grounds for refusal of the waiver 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, 14 November 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)