European Medicines Agency

Doc. Ref. EMA/749288/2009
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EUROPEAN MEDICINES AGENCY DECISION

of 23 December 2009

on the refusal of a Paediatric Investigation Plan and on the refusal of a deferral and on the refusal of a waiver for fentanyl citrate (EMEA-000481-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)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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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 30 January 2009 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 November 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said Regulation**,**

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

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the refusal of a Paediatric Investigation Plan and on the refusal of a deferral and on the refusal of a waiver,

(2) It is therefore appropriate to adopt a Decision refusing a Paediatric Investigation Plan,

(3) It is therefore appropriate to adopt a Decision refusing a deferral,

(4) 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 Paediatric Investigation Plan for fentanyl citrate, nasal spray, solution, nasal 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

A deferral for fentanyl citrate, nasal spray, solution, nasal 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 3

A waiver for fentanyl citrate, nasal spray, solution, nasal 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 4

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

Done at London, 23 December 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/PDCO/705150/2009
EMEA-000481-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE REFUSAL OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND A WAIVER

Scope of the application

Active substance(s):
Fentanyl citrate

Condition(s):
Acute pain

Pharmaceutical form(s):
Nasal spray, solution

Route(s) of administration:
Nasal use

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

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Nycomed Danmark ApS submitted for agreement to the EMEA on 30 January 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 5 March 2009.

Supplementary information was provided by the applicant on 4 September 2009.

A meeting with the Paediatric Committee took place on 11 November 2009.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to refuse the paediatric investigation plan in accordance with Article 18 of said Regulation, as the measures and the timelines are not appropriate to ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or some subsets, nor to adapt a paediatric formulation, or do not bring expected significant therapeutic benefit,

- to refuse a deferral in accordance with Article 21 of said Regulation,

- to refuse the granting of a waiver in accordance with Article 13 of said Regulation, for some of the subsets of the paediatric population and the above mentioned condition(s) as it does not meet the grounds detailed in Article 11(1) of said Regulation.

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 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 appendix.

London, 13 November 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)