European Medicines Agency

Doc. Ref. EMEA/615805/2009
P/208/2009

EUROPEAN MEDICINES AGENCY DECISION

of 30 October 2009

on the acceptance of a modification of an agreed Paediatric Investigation Plan for skimmed cow's milk powder (EMEA-000201-PIP01-08-M01) 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 decision P/107/2008 of the European Medicines Agency on 28 November 2008,

Having regard to the application submitted by DBV Technologies on 20 July 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 September 2009, in accordance with Article 22 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 of the European Medicines Agency has given, an opinion on the acceptance of changes to an agreed Paediatric Investigation Plan,

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an agreed Paediatric Investigation Plan.

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

HAS ADOPTED THIS DECISION:

Article 1

Changes to the agreed Paediatric Investigation Plan for skimmed cow's milk powder, cutaneous patch, cutaneous 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, are hereby accepted.

Article 2

This decision, that supersedes previous decision of the European Medicines Agency P/107/2008, as far as the agreed changes to the Paediatric Investigation Plan for skimmed cow's milk powder, cutaneous patch, cutaneous use, are concerned, is addressed to DBV Technologies, Pépinière Paris Santé Cochin, 29 rue du FbG St Jacques, 75014 - Paris, France.

Done at London, 30 October 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/570380/2009
EMEA-000201-PIP01-08-M01

OPINION OF THE PAEDIATRIC COMMITTEE ON THE ACCEPTANCE OF A MODIFICATION OF AN AGREED PAEDIATRIC INVESTIGATION PLAN

Scope of the application

Active substance(s):
Skimmed cow's milk powder

Condition(s):
Cow's milk allergy

Pharmaceutical form(s):
Cutaneous patch

Route(s) of administration:
Cutaneous use

Name/corporate name of the PIP applicant:
DBV Technologies

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, DBV Technologies submitted to the EMEA on 20 July 2009 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the EMEA decision P/107/2008 of 28 November 2008. The application for modification proposed changes.

The procedure started on 20 August 2009.

Scope of the modification

Timelines of the initially agreed clinical study are modified.

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Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree to the changes proposed by the applicant regarding the timelines of the paediatric investigation plan.

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

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

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

London, 18 September 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN AND THE SUBSET(S) OF THE PAEDIATRIC POPULATION AND CONDITION(S) COVERED BY THE WAIVER

A. CONDITION(S)

Cow's milk allergy

B. WAIVER

- **Condition**

The waiver applies to:

- Preterm newborn infants
- Term newborn infants (from birth to less than 28 days)

for cutaneous patch on the grounds that the specific medicinal product is likely to be ineffective.

- Children (from 6 to less than 12 years)
- Adolescents (from 12 to less than 18 years)

for cutaneous patch on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subsets.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Cow's milk allergy

- **Proposed PIP indication**

Cow's milk allergy

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 28 days to less than 6 years

- **Formulation(s)**

Cutaneous patch

- **Studies**

Area	Number of studies	Description
Clinical	1	A Multi-center Cross Sectional Study to evaluate the performance (sensitivity, specificity) of the diagnostic product in patients with clinical symptoms of suspected cow's milk allergy in comparison with the results of a Double Blind Placebo Control Food Challenge (DBPCFC) taking also into account specificity results in a control group of children apparently non allergic or tolerant to cow's milk.

Measures to address long term follow-up in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**May 2011**
Deferral for initiation of some or all studies contained in the paediatric investigation plan:	**No**
Deferral for completion of some or all studies contained in the paediatric investigation plan:	**No**