European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 28 November 2008

on the application for agreement of a Paediatric Investigation Plan for skimmed cow's milk powder EMEA-000201-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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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 DBV Technologies on 7 March 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 November 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 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, following a re-examination procedure of the Paediatric Committee's opinion according to art. 25(3) of Regulation (EC) No 1901/2006 as amended, has given a positive opinion,

(2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the Paediatric Investigation Plan,

(3) It is therefore appropriate to adopt a Decision granting 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 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, is hereby agreed.

Article 2

A waiver 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, is hereby granted.

Article 3

This decision is addressed to DBV Technologies, Pépinière Paris Santé Cochin - 29 rue du Faubourg Saint Jacques, 75014 – Paris, France.

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/533781/2008
EMEA-000201-PIP01-08

POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A REQUEST FOR AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN FOR (AFTER RE-EXAMINATION)

Scope of the application

Active substance:
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 16.1 of Regulation (EC) No 1901/2006 as amended, DBV Technologies submitted for agreement to the EMEA on 7 March 2008 a paediatric investigation plan for the above mentioned medicinal product.

An Opinion was adopted by the Paediatric Committee on 19 September for the above mentioned product. DBV Technologies received the Paediatric Committee Opinion on 24 September 2008.

On 22 October 2008 DBV Technologies submitted to the EMEA a written request, including detailed grounds for re-examination of the Opinion.

The re-examination procedure started on 23 October 2008.

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Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for the re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, revises its opinion and recommends, as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with article 18 of Regulation (EC) No 1901/2006 as amended,
- to grant a waiver for one or more subsets of the paediatric population pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended and concluded in accordance with Article 11(1)(a) of Regulation (EC) No 1901/2006, as amended, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population Article 11(1)(b) of Regulation (EC) No 1901/2006, as amended, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations.

The Icelandic and the Norwegian Paediatric Committee members do 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, 14 November 2008

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 2010**
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**