European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 14 October 2008

on the application for agreement of a Paediatric Investigation Plan for alanine, arginine, aspartic acid, cysteine/cystine, glutamic acid, glycine, histidine, isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, sodium chloride, potassium acetate, magnesium acetate, tetrahydrate, calcium chloride, sodium glycerophosphate, glucose, olive oil refined, soya-bean oil refined (EMEA-000112-PIP01-07) 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 Baxter World Trade SA/NV on 12 December 2007 under Article 16(1) of Regulation (EC) No 1901/2006 as amended,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 29 August 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended,

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

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

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency, 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.

HAS ADOPTED THIS DECISION:

Article 1

A Paediatric Investigation Plan for alanine, arginine, aspartic acid, cysteine/cystine, glutamic acid, glycine, histidine, isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, sodium chloride, potassium acetate, magnesium acetate, tetrahydrate, calcium chloride, sodium glycerophosphate, glucose, olive oil refined, soya-bean oil refined, Solution for infusion, 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 agreed.

Article 2

This decision is addressed to Baxter World Trade SA/NV, Boulevard de la Plaine 5, 1050 Brussels, Belgium.

Done at London, 14 October 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/452908/2008
EMEA-000112-PIP-07

POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A REQUEST FOR AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN FOR

Scope of the application

Active substance:
Alanine, arginine, aspartic acid, cysteine/cystine, glutamic acid, glycine, histidine, isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine
sodium chloride, potassium acetate, magnesium acetate, tetrahydrate, calcium chloride, sodium glycerophosphate, glucose, olive oil refined, soya-bean oil refined.

Condition(s):
Parenteral nutrition

Pharmaceutical form(s):
Solution for infusion

Route(s) of administration:
Intravenous use

Name/corporate name of the PIP applicant:
Baxter World Trade SA/NV

Basis for opinion
Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, Baxter World Trade SA/NV submitted for agreement to the EMEA on 12 December 2007 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 16 January 2008.

Supplementary information was provided by the applicant on 17 June 2008.

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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 agree the paediatric investigation plan in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended.

The Icelandic and the Norwegian Paediatric Committee member(s) agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan 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(es) and appendix(ces).

London, 29 August 2008

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

A. CONDITION(S) / DISEASE(S)

Parenteral nutrition

B. WAIVER

not applicable

C. PAEDIATRIC INVESTIGATION PLAN

Condition to be investigated

Parenteral nutrition

- **Subset(s) covered**

  Preterm newborn infants, term newborn infants, infants & toddlers, children and adolescents from 0 to less than 18 years

- **Formulation(s)**
  Solution for infusion

- **Studies / Measures**

Area	Subarea	Number	Description
Clinical	safety	1	Prospective, open-label, multicentre, non-comparative safety study of "Paediatric Triple Chamber Bag" solution administered intravenously in children from 0 to less than 18 years requiring parenteral nutrition.

Need for long-term follow-up on any potential safety issues in relation to paediatric use: no

Date of completion of the Paediatric Investigation Plan: by November 2008

A deferral has been granted: no