



European Medicines Agency

Doc. Ref. EMEA/624450/2008
P/120/2008

EUROPEAN MEDICINES AGENCY DECISION

of 1 December 2008

on the application for product specific waiver for omega-3-acid (85% ethyl esters of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in a ratio of 0.9-1.5), simvastatin (EMEA-000336-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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Sigma-Tau SpA on 23 July 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 17 October 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 a positive opinion,
- (2) 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 waiver for omega-3-acid (85% ethyl esters of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in a ratio of 0.9-1.5), simvastatin, soft capsule, oral route, 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 2

This decision is addressed to Sigma Tau SpA, Via Pontina Km 30,400, 00040 Pomezia, Rome, Italy.

Done at London, 1 December 2008

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/533988/2008
EMEA-000336-PIP01-08

**POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON
A PRODUCT-SPECIFIC WAIVER FOR**

Scope of the application

Active substance:

Omega-3-acid (85% ethyl esters of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in a ratio of 0.9-1.5), simvastatin

Condition(s):

Atherosclerotic cardiovascular disease following past myocardial infarction

Pharmaceutical form(s):

Soft capsule

Route(s) of administration:

Oral route

Name/corporate name of the waiver applicant:

Sigma-Tau SpA

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Sigma-Tau SpA submitted for agreement to the EMEA on 23 July 2008 an application for a waiver on the grounds set out in Article 11 of Regulation (EC) No 1901/2006 as amended for the above mentioned medicinal product.

The procedure started on 27 August 2008.

Opinion

The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report, to grant a waiver for all subsets of the paediatric population and all above mentioned conditions in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients

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

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

London, 17 October 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)