



**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology**

Date: October 19, 2006

To: Lisa L. Mathis, M.D., OND Associate Director
Pediatric and Maternal Health Team
Office of New Drugs (OND), CDER
and
M. Dianne Murphy, M.D., Director
Office of Pediatric Therapeutics (OPT), OC

Thru: Ann McMahon, MD, Deputy Director
for
Mark Avigan, M.D., C.M., Director
Division of Drug Risk Evaluation

From: Mary Ross Southworth, Pharm.D., Safety Evaluator
Division of Drug Risk Evaluation

Subject: Postmarketing Pediatric Adverse Event Review since OSE
Pediatric Exclusivity Review (September 2004)

Drug Name: Brevibloc (esmolol hydrochloride)

OSE RCM #: 2007-2130

EXECUTIVE SUMMARY

OPT requested a follow up review of AERS reports in pediatric patients associated with esmolol which were received after the last OSE review¹ in October 2004. An AERS search performed on October 19, 2007 revealed no new AERS cases in pediatrics (age range searched: 0 to 17).

¹ Sanders, Daniela, "One-Year Post-Pediatric Exclusivity Postmarketing Adverse Event Review", October 20, 2004, PID D030528.

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/s/

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11/2/2007 01:23:44 PM
DRUG SAFETY OFFICE REVIEWER

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11/2/2007 02:06:59 PM
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