

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*

**18-227 / S-012**

**ADMINISTRATIVE DOCUMENTS**  
**AND**  
**CORRESPONDENCE**

## **Project Manager's Labeling Review**

**NDAs:** 18-227/S-012 and S-013 FA

**Products:** Amidate (etomidate) Injection

**Sponsor:** Abbott

**Date submitted:** July 30, 1999 and March 11, 2003

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These submissions contain the Final Printed Labelings (FPLs) as requested in the approval letters dated February 26 and April 29, 1999. The FPLs submitted on July 30, 1999 and March 11, 2003, are identical to the labeling text approved on February 26 and April 29, 1999. The labelings should be acknowledged and retained.

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Parinda Jani  
Chief, Project Management Staff

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/s/

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Parinda Jani  
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NDA 18-227/S-012, S-013

Abbott Laboratories  
Hospital Products Division  
200 Abbott Park Road, D-389, J45-2  
Abbott Park, IL 60064-6157

Attention: Maryam Amiryaghoobi  
Specialist, Regulatory Affairs

Dear Ms. Amiryaghoobi:

We acknowledge receipt of your July 30, 1999, and March 11, 2003, submissions containing final printed labelings in response to our February 26 and April 29, 1999, letters approving your supplemental new drug applications for Amidate (etomidate) Injection..

We have reviewed the labelings that you submitted in accordance with our February 26 and April 29, 1999, letters and we find them acceptable.

If you have any questions, call Lisa Basham-Cruz, Regulatory Project Manager, at (301) 827-7410.

Sincerely,

*{See appended electronic signature page}*

Parinda Jani  
Chief, Project Management Staff  
Division of Anesthetic, Critical Care, and Addiction  
Drug Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

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/s/

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