CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20845/ S17

Trade Name: **INOMAX**

Generic Name: **Nitric Oxide**

Sponsor: **Mallinckrodt Hospital**

Approval Date: 10/09/2015

Indications: INOmax is a vasodilator indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents.

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CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	**X**
Other Action Letters	
Labeling	
Summary Review	
Officer/Employee List	
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	**X**
Chemistry Review(s)	
Environmental Assessment	
Pharmacology Review(s)	
Statistical Review(s)	**X**
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	
Other Review(s)	**X**
Administrative/Correspondence Document(s)	**X**

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20845/S-016, S-017

SUPPLEMENT APPROVAL

Mallinckrodt Hospital Products IP Limited
c/o: INO Therapeutics
Attention: Mary Ellen Anderson
Senior Director, Regulatory Affairs
Perryville III Corporate Park
53 Frontage Road, Third Floor, Box 9001
Hampton, NJ 08827

Dear Ms. Anderson:

Please refer to your Supplemental New Drug Applications (sNDAs) dated December 8, 2014 (S-016) and December 11, 2014 (S-017) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for INOmax (nitric oxide) for inhalation.

We acknowledge receipt of your amendments dated August 27, 2015 (S-016) and January 30 and February 13, 2015 (S-017).

The August 27, 2015 submission constituted a complete response to our June 4, 2015 action letter for S-016.

These "Prior Approval" supplemental new drug applications propose the following:

S-016
The removal of the 100 ppm nitric oxide concentration from the labeling and revisions to the **DOSAGE AND ADMINISTRATION** and **WARNINGS AND PRECAUTIONS** sections of the INOmax package inserts.

S-017
Revisions to the labeling based on the clinical study entitled "*Bronchopulmonary Dysplasia (BPD) in Preterm Infants Requiring Mechanical Ventilation or Positive Pressure Support on Days 5 to 14 After birth (IK-3001-BPD-301)*".

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at:

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