DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20845/S-018

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 Application (sNDA) dated October 13, 2015, received October 14, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for INOmax (nitric oxide) for inhalation.

This "Changes Being Effected" supplemental new drug application proposes to include a MR conditional triangle and an appropriate warning "Keep cylinder at 100 gauss or less" label.

APPROVAL

We have completed our review of this supplemental application and it is approved, effective on the date of this letter.

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:
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Brian Proctor, Regulatory Project Manager, at (240) 402-3596.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

NORMAN L STOCKBRIDGE
04/05/2016