

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20845

CORRESPONDENCE



DEPARTMENT OF HEALTH & HUMAN SERVICES

Z. McDonald

Food and Drug Administration
Rockville MD 20857

NDA 20-845

MAY 28 1999

INO Therapeutics, Inc.
Attention: Richard N. Williams, Ph.D.
54 Old Highway 22
Clinton, NJ 08809

Dear Dr. Williams:

We have received your new drug application (NDA) resubmitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: INOmax (nitric oxide)

Therapeutic Classification: Priority (P)

Date of Resubmission: May 24, 1999

Date of Receipt: May 26, 1999

Our Reference Number: 20-845

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on July 25, 1999 in accordance with 21 CFR 314.101(a).

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. All communications concerning this NDA should be addressed as follows:

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Cardio-Renal Drug Products, HFD-110
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Cardio-Renal Drug Products, HFD-110
Attention: Division Document Room
1451 Rockville Pike
Rockville, Maryland 20852-1420

NDA 20-845
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If you have any questions, please contact:

Ms. Zelda McDonald
Regulatory Health Project Manager
(301) 594-5333

Sincerely yours,

Natalia A. Morgenstern
Chief, Project Management Staff
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Archival NDA 20-845
HFD-110/Div. Files
DISTRICT OFFICE
HFD-110/Z.McDonald
sb/5/28/99
filename: 20845ac.doc

ACKNOWLEDGEMENT (AC)

McDonald

DEC 10 1997

NDA 20-845

Ohmeda Pharmaceutical Products Division Inc.
Attention: Ms. Priya Jambhekar
P.O. Box 804
110 Allen Road
Liberty Corner, NJ 07938-0804

Dear Ms. Jambhekar:

Please refer to your new drug application (NDA) for nitric oxide for inhalation, 400 ppm.

In reviewing your submission of June 16, 1997, our Medical Officer has raised a number of questions that require your attention. Our concerns with your submission are detailed as part of this correspondence (see enclosure).

Sincerely yours,

Natalia A. Morgenstern
Chief, Project Management Staff
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

Dr. Throckmorton's 11/24/97 review, pgs 138-248

cc:

Original NDA

HFD-110

HFD-110/ZMcDonald/12/4/97

sb/12/8/97

GENERAL CORRESPONDENCE

McDonald

OCT 27 1997

NDA 20-845

Ohmeda Pharmaceutical Products Division Inc.
Attention: Ms. Priya Jambhekar
P.O. Box 804
110 Allen Road
Liberty Corner, NJ 07938-0804

Dear Ms. Jambhekar:

Please refer to your new drug application (NDA) for nitric oxide.

In reviewing your submission of June 16, 1997, our Pharmacologist has raised a number of questions that require your attention. Our comments on your submission are detailed as part of this correspondence (see enclosure).

Sincerely yours,

Natalia A. Morgenstern
Chief, Project Management Staff
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

Dr. Oza's review dated October 10, 1997

cc:

Original NDA

HFD-110

HFD-110/ZMcDonald/10/21/97

sb/10/27/97

GENERAL CORRESPONDENCE

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