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CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER(S)

21-779

Trade Name: Ventavis Inhalation Solution 10 mcg/mL

Generic Name(s): (iloprost)

Sponsor: CoTherix, Inc.

Agent:

Approval Date: December 29, 2004

Indication: Provides for the treatment of pulmonary arterial hypertension

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APPLICATION NUMBER:

21-779

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Reviews / Information Included in this NDA Review.	
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Statistical Review(s)	X
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Approval Letter(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-779

CoTherix, Inc.
Attention: Ms. Klara A. Dickinson
Director, Regulatory Affairs
5000 Shoreline Court, Suite 101
South San Francisco, CA 94080

Dear Ms. Dickinson:

Please refer to your new drug application (NDA) dated June 30, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ventavis (iloprost) Inhalation Solution, 10 mcg/mL.

We acknowledge receipt of your submissions dated July 15 and 20, August 6, 10, and 18, September 8 and 30, October 5, 15 (two), 19, 22, and 28 (two), November 4, 16 (two), 18, and 24, and December 1, 10, 14, 15 (two), 17, 23, and 29, 2004.

This new drug application provides for the use of Ventavis (iloprost) Inhalation Solution for the treatment of pulmonary arterial hypertension (WHO Group I), as described in the attached approved package insert.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert) and submitted labeling (immediate container and carton labels and disc labeling dated December 23, 2004). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). These guidances specify that labeling is to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper. Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Cardio-Renal Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

Based on the drug substance stability data, an expiration date of not more than 36 months and a retest date of not more than (b) (4) nths are recommended for the drug substance, when stored frozen (b) (4).

An expiration date of 36 months is granted for the drug product stored at 20-25°C.

The Pediatric Research Equity Act is not applicable to drugs granted orphan drug designation.

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

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, please call:

Ms. Melissa Robb
Regulatory Health Project Manager
(301) 594-5313

Sincerely,

{See appended electronic signature page}

Robert Temple, M.D.
Director
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/

Robert Temple
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