DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-779/S-001 and S-002

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 supplemental new drug applications dated April 26 (S-001) and April 29, 2005 (S-002), 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 June 21 and August 8, 10, and 15, 2005.

These supplemental new drug applications provide inclusion of the results of "A Placebo-Controlled Study to Evaluate the Safety and Pilot Efficacy of Iloprost Inhalation Solution as Add-On Therapy with Bosentan in Subjects with Pulmonary Arterial Hypertension" (S-001) in the package insert and for an alternate nebulizer delivery device, the I-Neb Adaptive Aerosol Delivery (AAD) System for use with Ventavis (iloprost) Inhalation Solution (S-002).

We have completed our review of these applications, as amended. These applications are 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).

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, 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 this division and two copies of both the promotional materials and the package inserts directly to:

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

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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:

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

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

/s/

Norman Stockbridge

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