



MAY - 3 2006

Sharla K. Sutherland, Ph.D.
CV Technologies, Inc.
9411 20 Avenue NW
Edmonton, Alberta T6N 1E5
Canada

Dear Dr. Sutherland:

This is in response to your letter of April 19, 2006 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission stated that CV Technologies, Inc. is promoting the product "COLD-fX and the dietary ingredient CVT-E002 for "strengthening and/or strengthens the immune system."

This product is also promoted on your web site (<http://www.cvtechnologies.com>) as "The Cold & Flu Fighter." It is further promoted on web sites directly linked from your web site (<http://coldfx.com>) using claims such as "Suffering from a cold or flu? Fight Back!" and "Take COLD-fX to naturally strengthen your immune system, so cold & flu viruses don't take hold."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product (including the product name "Cold-fX" in light of the other claims made for the product) suggest that it is intended to treat, prevent, or mitigate diseases, namely the common cold and influenza. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

075 0163 LET881

Page 2 - Dr. Sharla K. Sutherland

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'SJW', written in a cursive style.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200



CV TECHNOLOGIES INC.

CV Technologies develops and manufactures evidence based natural health products for disease prevention and health maintenance.

2006-3704

Sharla Sutherland Ph.D.
Director, Regulatory & Scientific Affairs
Main: (780) 577-3745
Fax: (780) 432-7772
Email: sharla@cvtechnologies.com

April 19, 2006

APR 25 2006

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

Re: Statement for Dietary Supplement

Dear Sir or Madam:

This letter is submitted as required by Section 406(r)(6) of the Food, Drug & Cosmetic Act (FDC Act) for the purpose of notifying the Food and Drug Administration (FDA) of a certain statement being made in connection with the sale of a dietary supplement product marketed by this company.

The product brand name and the dietary ingredient for which certain statement is being made is COLD-fX and CVT-E002 respectively.

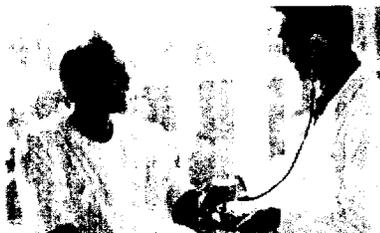
The text of the statement that is being made for the above product is listed below: strengthening and/or strengthens the immune system.

As Director, Regulatory & Scientific Affairs for CV Technologies, Inc., I certify that the information contained in this notification is complete and accurate and that CV Technologies, Inc. has substantiation that the above statement is truthful and not misleading.

Sharla K. Sutherland, Ph.D.

#1680





CV TECHNOLOGIES Inc.

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CV Technologies develops and manufactures evidence based natural health products for disease prevention and health maintenance



VISIT THE
CV TECHNOLOGIES' BRAND WEB SITES

Takes to
coldfx.com

PRESS RELEASES

CV TECHNOLOGIES – MAKER OF COLD-FX® - BEGINS TRADING ON THE TSX
Edmonton, AB, Canada - Mar. 20, 2006 [more](#)

CV TECHNOLOGIES ANNOUNCES GROWTH STRATEGIES AT AGM; U.S. PLANS FOR COLD-FX® UNVEILED
Edmonton, AB, Canada - Feb. 27, 2006 [more](#)

IN THE NEWS

'PREVENTION' MEDICINE ROOTED IN ANCIENT CHINA
Toronto Star - Apr. 8, 2006 [more](#)

EDMONTON'S COLD-FX® LOOKING TO THE U.S. MARKET
CBC News - Mon. Feb. 27, 2006 [more](#)

CV TECHNOLOGIES EYES FDA APPROVAL FOR COLD REMEDY.
Toronto, Canada (Reuters) - Mar. 21, 2006 [more](#)

COLD-FX® TARGETS U.S.
Canada Press (Globe and Mail) - Feb. 27, 2006 [more](#)

*CV Technol
is now listed*

PRODUCT TES

*Cold-FX is on the
front line year in
and out. It's not
just a cold, it's a
flu.*

Todd Marchant
Columbus Blue Jacke

CV TECHNO

Toronto Stock E

- Last Trade
- Change
- Volume
- Day High
- Day Low
- Ask
- Ask Size
- Bid
- Bid Size

Quotes are at least

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COLD-FX*

The Cold & Flu Fighter

HOW TO USE

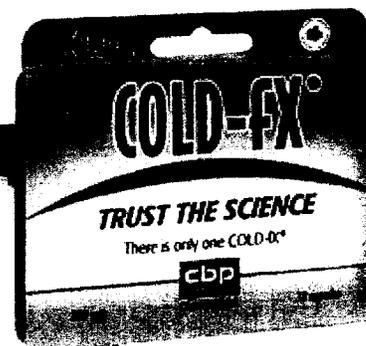
HOW IT WORKS

THE SCIENCE

Q&A

TESTIMONIALS

PREVENTION



Suffering from a cold or flu? Fight back!

Take COLD-FX to naturally strengthen your immune system, so cold & flu viruses don't take hold.

- ✓ Canada's #1 selling cold & flu remedy¹
- ✓ Clinically proven to prevent and treat respiratory illness²
- ✓ A favourite among elite athletes and celebrities. It's the product everyone is talking about!
- ✓ Take daily as a preventative or at the first sign of symptoms!

Click here for your chance
to win your year's supply of COLD-FX!



Buy it now >



← go to posiwell site

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¹AC Nielsen Marketrack, November 30, 2005

²7 clinical trials, including one US FDA regulated/Phase II clinical trial



COLD-fX



REMEMBER-fX



AD-fX



CELL-fX



MENTA-fX

Scientifically Certified Health Products. Get Healthy, STAY healthy.

FREE SHIPPING! US/Canada orders over \$60, International orders over \$100.

PosiWell Menu

PosiWell

Our Homepage

Our Products

Show All Products

COLD-fX

- Overview
- Quick Facts - FAQ
- Sports Training
- Travel and Stress
- Unique Advantages
- Testimonials
- Clinical Results

REMEMBER-fX

AD-fX

CELL-fX

MENTA-fX

PRESSURE-fX

Your Account

Cart and Check Out

Customer Sign-In

Change Account Info

Change Password

Order History

New Customers

Your Shopping Cart

Create An Account

Our Policies

Shipping Charges

Privacy and Security

100% Guarantee

Workplace Wellness

Sign-In

Program Overview

COLD-fX - Don't treat the symptoms, eliminate and prevent your colds and flu.

Benefits

COLD-fX is effective for both treatment and prevention of Cold and Flu. The Mechanism of Action studies



indicate that COLD-fX regulates both antigen specific acquired and innate immune systems to combat cold and flu viral infection. It will also have effectiveness in the following conditions:

- Travel, work related fatigue and stress: The immune system needs daily attention, because we use it up each day, at different rates. That is why COLD-fX is a safe, daily nutrient to assist in fighting virus and strengthening the immune.
- Complementary to Flu shot: as seen in seniors clinical trial.
- Diet change or Quitting smoking. Assists in strengthening the bodies defenses and physiological balances when undergoing a change in the body.

Evidence

COLD-fX has been **proven** to boost your natural ability to fight colds and flu, resulting in 89% reduction in cold and flu incidences. Research has shown that COLD-fX boosts the immune system and significantly decreases the incidence, frequency and duration of colds and flu.

- There have been 8 clinical trials conducted to date on COLD-fX, including two pivotal trials conducted in normal subjects between age 18 to 65 and an FDA approved, phase 2 double blind placebo, controlled trial with seniors – mean age of 79 and mean age of 64. The results of all the trials have shown that COLD-fX was well tolerated, safe and did not interact with existing medications or disease or other herbal products.
- IOC protocol testing on Olympic Athletes was conducted to show no induced or produced banned

Available Pack

Package	Price
COLD-fX Bottle (60 capsules)	\$22.99
COLD-fX Box (18 capsules)	\$10.99

All prices are in US!
Shipping to CA
Switch to Canada



Usage

- **For Immediate R**
Day 1 3 capsules 3 during the day
Day 2 2 capsules 3 during the day
Day 3 1 capsule 3 the day
- **For Daily Preven**
1 capsule 2 times ea

Contents

200 mg of CVT-E002, extract of oligosaccha polysaccharides deriv Panax quinquefolium American Ginseng)

Safety

- 10 years of consur 8 clinical studies show very safe and well to preventative and acu



substances. Today 300 Canadian Olympic athletes use COLD-fX.

- Two years of analysis with the Edmonton Oilers - today 27 NHL teams use COLD-fX preventatively at 2 capsules per day.

How COLD-fX works

COLD-fX contains concentrated immune-enhancing polysaccharides and oligosaccharides that boost the effects of human pathogen resistors such as natural killer cells, macrophages, cytokine and antibody producing cells. By increasing the function of these cells, your body can more effectively fend off a variety of viral invasions.

COLD-fX Advantages

COLD-fX has several **important advantages** over its competitors for acute treatment of cold and flu.

More Information

For more information on COLD-fX, please visit the **CV Technologies website**.

PosiWell's Best Sellers		
Click on a product image for details	Brief Description	Price (US Dollars)
	COLD-fX Bottle (60 capsules) Why just treat your symptoms? Eliminate and prevent your colds and flu.	\$22.99
	REMEMBER-fX Bottle (60 capsules) Scientifically proven to improve memory and restore alertness.	\$16.99
	CELL-fX Bottle (60 capsules) 10 times more concentrated than other shark cartilage.	\$21.99

All prices are in US dollars.
Within Canada? Switch to Canadian prices

Questions or Concerns about our products or website? Please email PosiWell Support

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is safe with high/low pressure patients, blood thinners, and autoimmune diseases.

- Cold-fX is even safe for diabetics as no glucose is in the blood.
- No known interactions have been found with any medications, disease modifying agents, or herbal products. Studies have indicated that Cold-fX is metabolized in the liver, creating no harmful byproducts in the body. Cold-fX® is as safe as a nutrient.