

# Division of Drug Marketing, Advertising, and Communications Enforcement Webinar

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# Mission

*"To protect the public health by assuring prescription drug information is truthful, balanced and accurately communicated. This is accomplished through a comprehensive surveillance, enforcement and education program, and by fostering better communication of labeling and promotional information to both healthcare professionals and consumers."*

# Enforcements

## Warning Letters

- Bromday
- Multikine
- Vyvanse

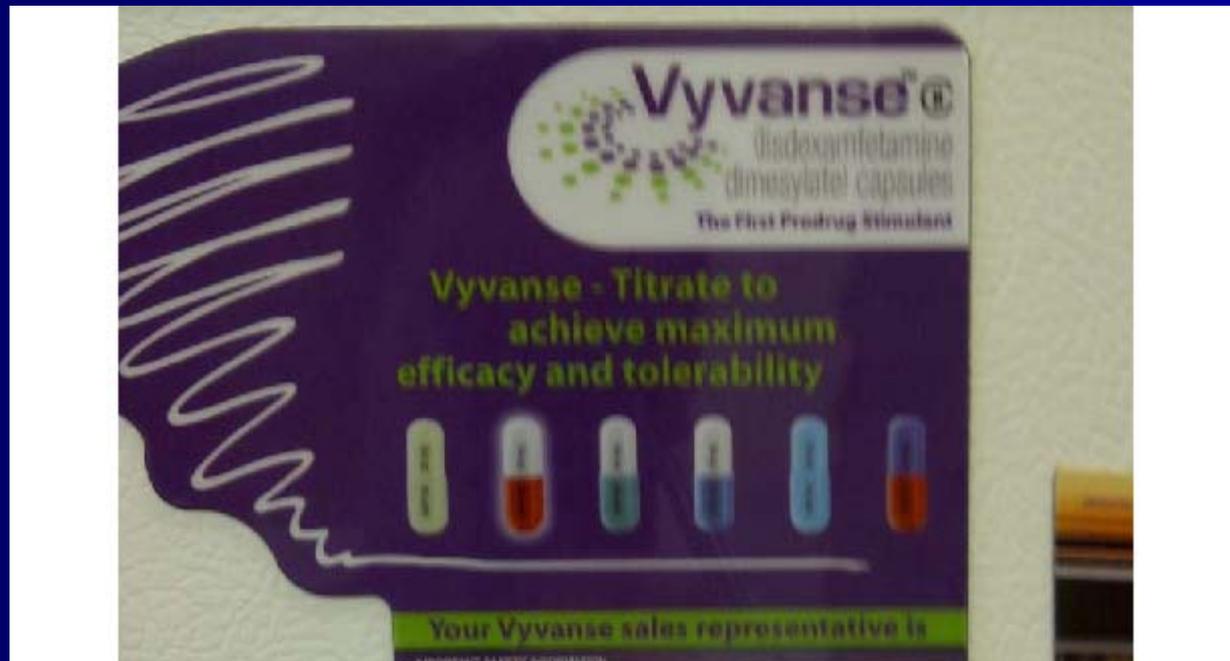
## Untitled Letters

- Acanya
- Atelvia
- Focalin XR
- KRX-0401
- Pexeva
- Solaraze
- Trisenox

# Violations include:

- Omission/Minimization of Risk
- Unsubstantiated Claims
  - Unsubstantiated Superiority Claims
- Broadening of Indication
- Overstatement of Efficacy
- Omission of Material Facts
- Promotion of an Investigational Drug
- Misleading Claims (dosing, compliance)
- Failure to Submit Under Form FDA-2253

# Vyvanse



# Pexeva

Help your patients weather their storm...

**Mood disorders can lead to overlapping symptoms—  
choose from the comprehensive coverage your patients need**

- As many as 75% of patients with MDD also exhibit a range of anxiety symptoms or distinct disorders!

General Anxiety Disorder

OCD

Major Depressive Disorder

PD

Repetitive checking

Restlessness

Fear of contamination

Irritability

Suicide ideation

Sleep disturbance

Muscle tension

Fatigue

Loss of interest in sex

Shortness of breath

Chest pain

Palpitation

**Pexeva**<sup>®</sup> Tablets  
(paroxetine mesylate)

**BROAD-SPECTRUM THERAPY**

These selected symptoms of GAD, MDD, OCD, and PD are used here only as examples.

PFXEVA is indicated for the treatment of MDD, GAD, Panic Disorder, and OCD.

Please see Important Safety Information, including Black Boxed WARNING. Please see accompanying full Prescribing Information including WARNINGS—Clinical Worsening and Suicide Risk; Usage in Pregnancy; Teratogenic and Nonteratogenic Effects.

# Focalin XR

Muniz et al 2008 and Silva et al 2008

When considering an ADHD medication

**Think Focalin XR first for a fast start**

**TWO CLINICAL STUDIES EVALUATED THE EFFICACY AND SAFETY OF FOCALIN XR<sup>®</sup> COMPARED WITH CONCERTA<sup>®</sup> IN A LABORATORY CLASSROOM SETTING**

CLINICAL HIGHLIGHTS FROM:

**STUDY 1: Efficacy and Safety of Extended-Release Dexamethylphenidate Compared With d,l-Methylphenidate and Placebo in the Treatment of Children With Attention-Deficit/Hyperactivity Disorder: A 12-Hour Laboratory Classroom Study**

Muniz E, Biedt M, Mao A, McCasale K, Faraone S, Silva P. *J Child Psychol Psychiatr*. 2008;49(12):146-155.

**STUDY 2: Treatment of Children With Attention-Deficit/Hyperactivity Disorder: Results of a Randomized, Multicenter, Double-Blind, Crossover Study of Extended-Release Dexamethylphenidate and d,l-Methylphenidate and Placebo in a Laboratory Classroom Setting**

Silva P, Biedt M, McCasale K, Faraone S, Biedt M, Mao A. *Psychopharmacol Bull*. 2008;44(1):101-11.

**Primary efficacy end point in both studies:** change from baseline in SKAMP combined score between Focalin XR 20 mg and Concerta 36 mg at 2 hours postdose.<sup>1,2</sup>

See www.focalinxr.com for additional information.

FOCALIN XR is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in patients aged 6 years and older. FOCALIN XR is indicated as an integral part of a total treatment program for ADHD that may include other measures, psychological, educational, social for patients with this syndrome. Appropriate education, placement, assessment and psychosocial interventions are often helpful. The effectiveness of FOCALIN XR for long-term use, ie, more than 7 weeks, has not been systematically evaluated in controlled trials.

#### Important Safety Information

##### WARNING: DRUG DEPENDENCE

FOCALIN XR should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence, with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parental abuse. Careful supervision is required during withdrawal from abusive use, since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

<sup>1</sup>See see back cover for additional Important Safety Information.  
<sup>2</sup>For more information, including prescribing information, including boxed WARNING and Medication Guides.

ONCE-DAILY  
**Focalin XR**  
dexamethylphenidate HCl extended-release  
**First line. Fast start. Full day.**

# Acanya

Acanya  
(Clindamycin Phosphate and  
Benzoyl Peroxide) Gel, 1.25%/2.25%  
Ready-to-Use 30g Pump

Power to please

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About Acanya Gel | About acne | Before-and-after | Special offers | Healthcare professionals

An acne medicine that's  
made to be loved

Acanya® Gel—the once-daily topical prescription treatment with the power to treat your acne without over-drying your skin.

Acanya Gel is proven to work. Studies show that Acanya Gel was proven to treat blackheads, whiteheads, and inflamed acne on the face.

Acanya Gel is gentle to skin, too. The water-based gel contains no alcohol or parabens that may contribute to stinging or burning. Fragrance-free Acanya Gel goes on smoothly, dries quickly, and leaves no residue.

Now in a convenient pump.



Get instant Savings

Patients pay no more than \$25 every time they fill a prescription for Acanya Gel.

Tell a friend about Acanya Gel, and receive a coupon for 25% off your next purchase of Acanya Gel. [View details](#)

View instructions for using Acanya Gel



**Indication and Important Safety Information:** Acanya® Gel is indicated for the topical treatment of acne vulgaris in patients 12 years of age or older. Side effects may include redness, itching, stinging, burning, and stinging. Do not use Acanya Gel if you are allergic to clindamycin, or if you have a history of inflammation of the skin (eczema). Children, the antibiotic in Acanya Gel, may cause diarrhea. If you experience diarrhea, stop using Acanya Gel immediately and contact your doctor. Avoid using tanning beds or sun lamps, and limit your time in sunlight after applying Acanya Gel. Avoid applying Acanya Gel to mouth, eyes, or nose, or on lips.

Acanya Gel is a prescription medication. See your doctor for more information.

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# Solaraze

In the treatment of actinic keratoses...

SOLARAZE® Gel:

**Delivers the clearance.  
Preserves the appearance.**

- ★ 95% clearance of target lesions at 1 year posttreatment<sup>1</sup>
- ★ Significant clearance in all targeted body areas<sup>2,3</sup>
- ★ Effectively treats subclinical lesions within target area<sup>4</sup>
- ★ Well tolerated<sup>2,5,6</sup>
- ★ Can be used on all areas of the body<sup>2,3</sup>
- ★ Can be used on immunocompromised patients<sup>2</sup>
- ★ #1-prescribed AK treatment in Europe and Australia<sup>7</sup>

SOLARAZE® Gel is indicated for the topical treatment of actinic keratoses (AK).

In clinical trials, the most common adverse reactions involved the skin and included contact dermatitis, rash, dry skin and exfoliation.

The majority of these reactions were mild to moderate in severity, and resolved upon discontinuation of therapy.

**SOLARAZE® GEL**  
diclofenac sodium-3%

Please see additional Selected Safety Information inside and on back cover.  
Please see attached full Prescribing Information.

# Trisenox

Trisenox (arsenic trioxide) TABLETS

TRISENOX (arsenic trioxide) TABLETS

TRISENOX: Standard of Care in Relapsed or Refractory APL<sup>1</sup>

Watch the video

core

Core is a leading provider of clinical research solutions for pharmaceutical and biotech companies.

### APL Physicians' Network

Join our physicians' network to receive the latest information on clinical trials and research.

### AML vs APL

Learn the difference between Acute Myeloid Leukemia (AML) and Acute Promyelocytic Leukemia (APL).

### Downloadable Resources

Downloadable resources including brochures and patient education materials.

### TRISENOX

- Trisenox is a standard of care in relapsed or refractory APL.
- Trisenox is the only oral arsenic trioxide available in the United States.
- Trisenox is a standard of care in relapsed or refractory APL.
- Trisenox is a standard of care in relapsed or refractory APL.

- ### References
1. Grignani F, et al. Arsenic trioxide in acute promyelocytic leukemia. *N Engl J Med*. 2000;343:1713-22.
  2. Grignani F, et al. Arsenic trioxide in acute promyelocytic leukemia. *N Engl J Med*. 2000;343:1713-22.
  3. Grignani F, et al. Arsenic trioxide in acute promyelocytic leukemia. *N Engl J Med*. 2000;343:1713-22.
  4. Grignani F, et al. Arsenic trioxide in acute promyelocytic leukemia. *N Engl J Med*. 2000;343:1713-22.
  5. Grignani F, et al. Arsenic trioxide in acute promyelocytic leukemia. *N Engl J Med*. 2000;343:1713-22.
  6. Grignani F, et al. Arsenic trioxide in acute promyelocytic leukemia. *N Engl J Med*. 2000;343:1713-22.
  7. Grignani F, et al. Arsenic trioxide in acute promyelocytic leukemia. *N Engl J Med*. 2000;343:1713-22.
  8. Grignani F, et al. Arsenic trioxide in acute promyelocytic leukemia. *N Engl J Med*. 2000;343:1713-22.
  9. Grignani F, et al. Arsenic trioxide in acute promyelocytic leukemia. *N Engl J Med*. 2000;343:1713-22.
  10. Grignani F, et al. Arsenic trioxide in acute promyelocytic leukemia. *N Engl J Med*. 2000;343:1713-22.

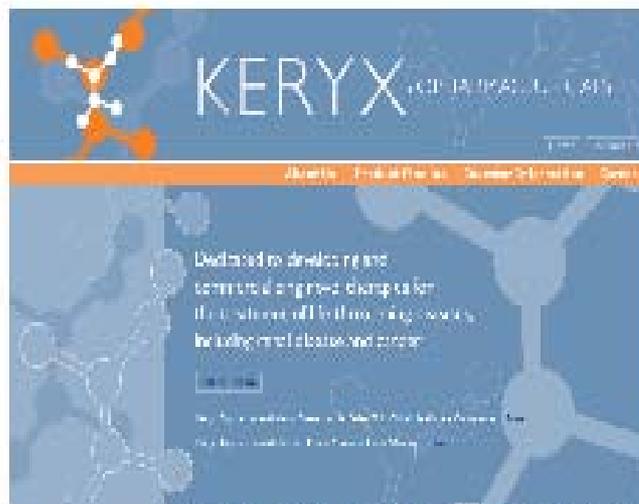
TRISENOX is a standard of care in relapsed or refractory APL. Trisenox is the only oral arsenic trioxide available in the United States. Trisenox is a standard of care in relapsed or refractory APL. Trisenox is a standard of care in relapsed or refractory APL.

### TRISENOX

Trisenox (arsenic trioxide) TABLETS

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# KRX-0401



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CD BPOBACU, L. A. S.

# Bromday

**ATTENTION: QD BROMDAY™ Replaces XIBROM™**

XIBROM will no longer be shipped to wholesalers after February 28, 2011

**IMPORTANT  
UPDATE**

The **FIRST and ONLY** QD  
ophthalmic NSAID for use  
in cataract surgery<sup>1</sup>

**Bromday™**  
(bromfenac ophthalmic  
solution) 0.09%



**Order BROMDAY Today**

- Approximately 3.1 million cataract surgeries are performed annually<sup>2</sup>
- The ophthalmic NSAID market is a \$320 million market<sup>3</sup>
- More than 2.6 million ophthalmic NSAID prescriptions are written annually<sup>4</sup>

#### STOCKING INFORMATION

Product	Packaging	NDC#
BROMDAY	1.7 mL	60725-029-11

BROMDAY (bromfenac ophthalmic solution) 0.09% is indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

The most commonly reported adverse reactions in 2-4% of patients were abnormal sensation in eye, conjunctival hyperemia and eye irritation (including burning/stinging).

Please see full prescribing information on reverse.

Rx only



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# Multikine

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**For Physicians**

**For Patients**

**Multikine Phase 3 Study**



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CEL SCI is dedicated to improving the treatment of cancer and other diseases by unleashing the power of the immune system, the body's natural and most potent defense system.

Our flagship product, Multikine®, is the first immunotherapeutic agent being developed as a first line standard of care treatment for cancer. Multikine stimulates the activities of a healthy patient's immune system, and enhances and amplifies the body's own anti-tumor immune response.

Multikine® has been cleared in the U.S. and Canada for a groundbreaking global Phase III clinical trial in advanced primary (not yet treated) head and neck cancer patients. This trial is expected to be the largest head and neck cancer clinical study ever conducted.

It is also the first Phase III study in the world in which immunotherapy is given to cancer patients first, i.e. prior to any other existing conventional treatment for cancer, including surgery, radiation and/or chemotherapy. This is significant because conventional therapy weakens the immune system, and likely compromises the benefits of immunotherapy. Multikine works by activating the patient's immune system because it is given before the reverses of conventional care in the advanced cancer clinical trial.

Multikine® is a different kind of weapon in the battle against cancer. Multikine is a defined mixture of cytokines. It is the first of a new class of semi-immunotherapy called combination immunotherapy, possessing both active and passive properties.

Multikine® is the only immunotherapy that is able to directly kill the tumor cells themselves in a targeted way, as well as evaluate the patient's own anti-tumor immune response. Multikine is not toxic because it works with the body's immune system. Multikine will be manufactured in GMP facilities at the San Antonio manufacturing facility owned by Biogen. See news about Multikine.

CEL SCI's other immunotherapy products (i.e. IL-2, GM-CSF) are ongoing and currently in various stages of pre-clinical development. These products have been shown to protect animals from infection or disease by a number of viruses and zoonotic agents. CEL SCI has shown considerable promise as a therapeutic vaccine for H5N1 avian influenza. The initial tests in animals showed that CEL 2009 is equivalent or possibly superior to Physalis in killing

**Special Highlights**

- ▶ Learn about our global Multikine Phase 3 clinical study
- ▶ New independent research report on CEL SCI
- ▶ CEL SCI and Swine Flu (H1N1) Antidote
- ▶ Multikine® named 1 of 10 Future Blockbusters

**Letter to Shareholders**

*All the end of last year we succeeded to report that we started our second Phase III trial for Multikine® in advanced primary head and neck cancer. This study is designed to demonstrate that our novel approach...*

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**Recent Press Releases**

**APRIL 29, 2011**  
NEWSWIRE (7/1) (PT)  
 Corporation Receives Final Cancer Government Approval to Commence Phase III Clinical Trial of Multikine in Head and Neck Cancer

**APRIL 28, 2011**  
NEWSWIRE (CEL-SCI)  
 Committee Please to Clinical Trial in Head and Neck Cancer in India

**APRIL 17, 2011**  
NEWSWIRE (7/1) (PT)  
 Corporation's Chief Scientific Officer to Present Data Supporting Pre-clinical Preclinical Trials for Cancer at World Vaccine Conference on April 14th

**APRIL 7, 2011**  
NEWSWIRE (CEL-SCI)  
 Corporation Receives Government Approval in India to Commence Phase III Clinical Trial of Multikine in Head and Neck Cancer

**MARCH 30, 2011**  
NEWSWIRE (CEL-SCI)

# Thank you!

- Webinar Feedback
  - [CDERDDMACenforceweb@fda.hhs.gov](mailto:CDERDDMACenforceweb@fda.hhs.gov)