

# Your Annual OTC Update

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## Disclosures

Stefanie Ferreri and Dan Krinsky declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

## CPE Information

- Target Audience: Pharmacists and Pharmacy Technicians
- ACPE#: 0202-0000-19-091-L01-P/T
- Activity Type: Knowledge-based

## Learning Objectives

At the completion of this knowledge-based activity, participants will be able to:

1. List products that entered or were removed from the over-the-counter (OTC) marketplace during 2018 and the first quarter of 2019.
2. Summarize information that should be provided to patients about these new or discontinued OTC products.

## Assessment Questions

1. All of the following are key points to share with a consumer interested in buying Primatene Mist EXCEPT:
  - A. Talk with your pharmacist or doctor before using if you are taking a medicine for allergies, such as pseudoephedrine.
  - B. Do not use unless your doctor said you have asthma
  - C. It is important to use this every 4 hours for maximal relief
  - D. Talk with your pharmacist or doctor before using if you are taking a medicine for depression

## Assessment Questions

2. Which of the following is the active ingredient in ZzzQuil PureZZZs?
- A. Diphenhydramine
  - B. Melatonin
  - C. Doxylamine
  - D. Passion Flower

## Assessment Questions

3. Drkids offers products that are:
- A. Flavored to be compatible with all kids' tastes
  - B. Packaged with a dosing spoon and dosing syringe
  - C. Homeopathic to eliminate risk
  - D. Single-use vials with premeasured doses

## Assessment Questions

4. Kratom is an ingredient in many recalled products because it is thought to have which property?
- A. Muscle-building
  - B. Sexual enhancement
  - C. Treat opioid addiction
  - D. Weight loss



## Statistics

### Recent assessment of OTC medication sales by Consumer Healthcare Products Association (CHPA):

- >\$34.3 billion in revenue in 2017
- Factors contributing to growth/popularity: ***convenience and availability***

OTC Category	Rank (\$ Sales)	2017 (in millions)
Upper Respiratory	1	\$8,647
Analgesics, Internal (includes other pain products)	2	\$4,171
Heartburn	3	\$2,653
First Aid	4	\$2,185
Oral Antiseptics and Rinses	5	\$1,454
Laxatives	6	\$1,304
<u>Suncare</u>	7	\$1,227
Lip/Oral Treatment	8	\$1,144
Anti-Smoking Products	9	\$1,008
Analgesics, External	10	\$858
Eye Care	11	\$848
Female Contraceptives, itch/yeast, other	12	\$716
Acne	13	\$607
<b>TOTAL</b>		<b>\$34,327</b>

Website: OTC Sales by Category 2014-2017. Consumer Healthcare Products Association. <https://www.chpa.org/OTCsCategory.aspx>.

## New Products

### **Primatene Mist:**

- Reintroduced November 2018
- Active ingredient: Epinephrine 0.125 mg per inhalation

### **Per manufacturer (mfr): *Uses***

- For temporary relief of mild symptoms of intermittent asthma
  - wheezing
  - tightness of chest
  - shortness of breath

<https://www.primatene.com/drug-facts.aspx>

## New Products

### Primatene Mist:

#### More information per mfr:

- “Do not use unless your doctor said you have asthma”
- **“Ask a doctor or pharmacist before use if you are**
  - taking prescription drugs for asthma, obesity, weight control, depression, or psychiatric or emotional conditions
  - taking any drug that contains phenylephrine, pseudoephedrine, ephedrine, or caffeine (such as allergy, cough-cold, or pain)”

<https://www.primatene.com/drug-facts.aspx>

## New Products

### Advil products:

- Advil Migraine: “solubilized ibuprofen capsules, 200mg”
- Advil Liqui-Gels minis: 33% smaller capsule – easier to swallow

<https://www.advil.com/advil-migraine>

<https://www.advil.com/advil-liqui-gels-minis>

## New Products

### **ThermaCare<sup>®</sup> Ultra Pain Relieving Cream**

- 4 ingredients “that help stop pain fast”:
  - Camphor, Menthol, Capsaicin, Methyl Salicylate

<https://www.thermacare.com/ultra-pain-relieving-cream>

## New Products

### New Robitussin Products:

- Maximum Strength Honey Cough + Chest Congestion DM
  - Dextromethorphan (DM) and Guaifenesin
- Maximum Strength Honey Nighttime Cough DM
  - DM and Doxylamine
- $\geq 12$  years of age

<https://www.robitussin.com/products/maximum-strength-honeycough-chest-congestion-dm>

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<https://www.robitussin.com/products/maximum-strength-honey-nighttime-cough-dm>

## New Products

### **ZzzQuil PureZZZs – new product is a nondrug sleep aid**

- Pure ZZZs Blend Gummies
- Primary ingredient: Melatonin – 2mg per 2 gummies
- Also contains a “Pure Zzzs™ Blend” which includes the following:
  - Chamomile, lemon balm, valerian root, lavender

<https://vicks.com/en-us/shop-products/zzzquil-sleep-aid/pure-zzss-melatonin-gummies>



## New Products

### Mucinex Cold & Flu All in One

- New multi-symptom formula that addresses the following symptoms: headache and body pain, nasal congestion and sinus congestion and pressure, cough and chest congestion and sore throat and fever.

<b>Ingredient</b>	<b>Amt per caplet or liquid gel</b>	<b>Amt per 20ml (DAYTIME liquid prep)</b>	<b>Amt per 20ml (NIGHT TIME liquid prep)</b>
Acetaminophen	325 mg	650 mg	650 mg
Dextromethorphan	10 mg	20 mg	
Guaifenesin	200 mg	400 mg	
Phenylephrine	5mg	10mg	10 mg
Diphenhydramine			25 mg

## New Products

### Theraflu PowerPods

- Daytime and nighttime options
- **Daytime:** Multi-ingredient products (acetaminophen 650mg, dextromethorphan 20mg, phenylephrine 10mg) in unique dosage form
- PowerPods can be used with single-serve coffee machines to brew a cup of Theraflu.
- Mfr recommends rinsing with 8 oz water after use.

[https://www.theraflu.com/products/?gclid=CJSx6daww-ACFfaGxQId\\_OkDrQ&gclsrc=ds](https://www.theraflu.com/products/?gclid=CJSx6daww-ACFfaGxQId_OkDrQ&gclsrc=ds)

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[https://www.theraflu.com/products/?gclid=CJSx6daww-ACFfaGxQId\\_OkDrQ&gclsrc=ds](https://www.theraflu.com/products/?gclid=CJSx6daww-ACFfaGxQId_OkDrQ&gclsrc=ds)

## New Products

### **Releev one-day cold sore symptom treatment.**

- Proprietary botanical formulations Viracea 1 and Viracea 2 which include Benzalkonium chloride and Echinacea.

<https://releev.com/>

## New Products

- **According to the mfr., Releev:**
  - Cleanses the sores
  - Dries the sores
  - Prevents secondary infections
  - Clears symptoms within 24 hours of initial use.
- **Application sites:**
  - On the sores
  - Inside the lips
  - On oral mucosa
- **Selling points compared with competitor:**
  - Frequency of use: three or four times a day (vs more for Abreva [docosanol]).
  - Can be used in individuals > 2 years of age (vs > 12 for Abreva [docosanol]); mfr still recommends discussing with doctor prior to use in children.

<https://releev.com/>

## New Products

### Salonpas Pain Relief Patch

– Larger Size

#### *Active Ingredients*

- Menthol 3%
- Methyl salicylate 10%

<http://salonpas.us/product/salonpas-pain-relief-patch-large>

## New Products

### Ear Pain MD and Ear Pain MD for Kids by Eosera

- Designed to relieve ear pain due to any situation
- Active ingredient: 4% lidocaine.
- 2 products: strictly for marketing purposes – adults and kids ( $\geq 2$  yrs)

**Directions:** Tilt head to the side slightly and apply 4-6 drops in the ear canal. The drops should start working within 3-5 minutes, with maximum pain control around 30 minutes.

- Recommend: Every 3-4 hours; not more than 3-4 times/day
- Ear Pain MD is for external use only in the outer ear canal.

## New Products

### Earwax MD for Kids

- Per mfr: earwax cleared with one application within 15 to 30 minutes.
- Complex directions for use (video on website) + info on packaging.
- Product uses a ‘dual-action’ mechanism to dissolve human cerumen.
  - Bicarbonate system disrupts the wax ester and fatty acid lipid components; byproducts more water soluble
  - Glycolic acid system chelates calcium ions from the calcium-dependent cell adhesion molecules causing disruption of cadherins allowing the keratin sheet cells to break apart.

<https://earcaremd.com/pages/earwaxmd>

<https://bmcearthroatdisord.biomedcentral.com/articles/10.1186/s12901-017-0038-8>



## New Products

### **Drkids is offering unique line of pediatric OTC products**

- Single-use vials of OTC products with premeasured doses
- Eliminates the need for a measuring device
- Products: Allergy Relief, Cough & Cold, Chest Congestion, Respiratory Support, Night-Time Respiratory Support and Respiratory Support Immune products.
- Each package includes 20 vials.
- Sugar-, alcohol- and dye-free.

<https://www.mydrkids.com/products>

## New Products

### Products are for a very narrow patient population

- Example: Pain and Fever product for kids:
  - Weight 24-35 pounds (lbs)/ages 2-3
  - Dosing: 1 single-use vial Q4H while symptoms last. Do not exceed 5 vials/24 hrs
  - 160 mg/5ml (standard concentration)
- Directions:
  - **Flick** the tip before opening so liquid descends
  - **Twist** the tip until open and discard immediately
  - Place open end into child's mouth and **Squeeze** to dispense all liquid and discard.

## New Products

### **Drkids: Cough and Cold product for kids:**

Ingredients: Dextromethorphan and Guaifenesin

Dosing based on age:

4-6 years: 1 vial q4h

6-11 years: 1-2 vials q4h

12 and older: 2-4 vials q4h

## New Products

### From the mfr:

- “We believe that we are the most innovative pediatric OTC line of products in the market”
- “Consumers do not have to worry about whether they over- or under-medicated their children. The pre-measured vials take all the guessing out of dosing and is the safest way for adults to provide medication to their kids.”

# New Products

## Dr. Hana's Nasopure Nasal Wash System

- Benefit, per mfr: user can be standing straight up and maintain a natural head position without bending or twisting.
- Other devices flush upward – creates a 'drowning' feeling
- ***"Did you know"*** (from mfr): — "Your nose filters 10,000 liters of air per day, produces 1 pint to 1 quart of mucus per day, so it just makes sense to clean your personal filter."
- "Nasopure products are made in the United States, contain 100% recyclable BPA-free material and are assembled by adults with disabilities."

## New Products

### Xlear sinus solutions products

- Sinus product line: xylitol is the primary ingredient
- Mfr claim: ingredient “will kill off bacteria in the throat and nose that other traditional ingredients will not fully remove.”

### Evidence that may support this claim:

- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC162832/pdf/391820.pdf>
- Kontiokari T, et al. Effect of xylitol on growth of nasopharyngeal bacteria in vitro. [Antimicrob Agents Chemother](#). 1995 Aug; 39(8): 1820–1823.

## New Products

- **DiaResQ®**: Food for Special Dietary Use that contains immune factors, micronutrients, and macronutrients
- Indicated to support gastrointestinal (GI) health
- Goal is to address underlying cause of diarrhea — not just manage symptoms.

## New Products

### **PainBloc24<sup>®</sup>**

- Active ingredient: topical capsaicin 0.25%
- Recommended directions: Apply to affected area(s) Q 12-24 hrs
- Mfr suggests one application can last for up to 24 hours
- Roll-on applicator: arthritis-friendly
- Odor-free



## New Products

### Top Up Tonic

- Designed for women to help offset the adverse effects (AEs) of hormonal birth control.
- Contains essential nutrients that are depleted with hormonal birth control products.
- May help relieve common AEs associated with birth control, including bloating, fatigue, headaches, mood swings, and nausea.
- **Ingredients**: antioxidants, minerals, and vitamins, including: vitamin B complex, vitamin C, vitamin E, and inulin, CoQ10, n-acetylcysteine, l-tyrosine, and a probiotic blend

[www.hello.me](http://www.hello.me)

## New Products

### **Honu: the first sunscreen with a patented WAND sprayer**

- First sunscreen product to use a spray wand to help protect hard-to-reach spots against damage from prolonged sun exposure.
- SPF 50 sunscreen is waterproof for up to 80 minutes
- Active Ingredients: Avobenzone 3%, Homosalate 15%, Octisalate 5%, and Octocrylee 8 %. Claimed to be environmentally friendly.
- Also contains aloe, antioxidants, and coconut oil – all for skin hydration
- For those ‘flying solo’ on the beach!

## New Products

### Finess Soft Patch

- First OTC product promoted to stop bladder leakage “in both a comfortable and discreet way”.
- From the mfr website: “Finess is placed over the urethral opening, and the gentle hydrogel adhesive seals it in place, preventing any urine from leaking out until it’s removed. When increased abdominal pressure is placed on the bladder – during a coughing fit or a Pilates class– Finess prevents the urine from escaping. Women no longer need to walk around with wet underwear or a bulky, damp pad – they can resume or continue doing the activities they love. ***With Finess you can laugh often, worry less, and live more*** (emphasis added).”

[www.havefiness.com](http://www.havefiness.com)

## New Products

### Omeprazole ODT

- Omeprazole Delayed Release Orally Disintegrating Tablets (ODT) 20 mg
- Available for store branding
- Uses 'MeltTech' technology (to create ODT properties)

## New EYE Products

### **Ocuvite Blue Light Eye Vitamin**

Nutritional supplement containing the 2 carotenoid pigments found in the eye (per softgel):

- Lutein 25 mg
- Zeaxanthin 5 mg

Protects the eyes against blue light from digital devices. Blue light can enter the macula, the part of the eye responsible for central vision, and cause damage.

<https://www.ocuvite.com/product/ocuvite-blue-light/>

## New EYE Products

### Ocuvite Adult 50+ MiniGels

- Daily eye vitamin, target audience is those 50+, to help restore key essential eye nutrients
- Key ingredients (per MiniGel):
  - Vitamins C and E
  - Zinc
  - Omega-3 Fatty Acids (EPA and DHA) (250mg total)
  - Lutein (5 mg)
  - Zeaxanthin (1 mg)

<https://www.ocuvite.com/product/ocuvite-adult-50/>

## New Products: What's next?!

Heineken's Lagunitas introduces: **New product: Hi-Fi Hops**

- 'IPA-inspired' sparkling water ***infused with cannabis***

Available in two strengths:

- Lighter version: 5mgs of THC (tetrahydrocannabinol)
- Stronger version: 10mgs of THC
- Other players in this space: Corona, Blue Moon, some California wine makers

## New Products: Home Testing and Devices

### Natural Cycles:

- Developed an algorithm that analyzes the temperature (temp) measurements entered into the app by the user to detect ovulation. Goal is to identify:
  - **Green** days, when no protection is needed
  - **Red** days, when the user should use condoms or abstain from sex to prevent a pregnancy.
- Requirement: basal thermometer that measures temp to 2 decimal points.
- Measure temp every morning before getting out of bed at least 5 days/week.

<https://www.naturalcycles.com/en>



## New Products: Home Testing and Devices

### Natural Cycles:

- “Smart Algorithm” determines daily fertility status.
- Adapts to individual unique cycle patterns by learning over time as more data are entered.
- Accounts for sperm survival, variation in cycle length, ovulation day and temperature fluctuations
- For use in premenopausal women at least 18 years of age
- Claim 93% effectiveness, based on study of > 15,500 pts
  - Scherwitz EB, et al. Perfect-use and typical-use Pearl Index of a contraceptive mobile app. *Contraception*; 2017; 96: 420–425.  
<https://doi.org/10.1016/j.contraception.2017.08.014>

## New Products: Home Testing and Devices

### Quell: a pain relief device

- Uses neurostimulation to relieve chronic back, arthritic, nerve, leg, and foot pain.
- Device is strapped to the appropriate place on the body
- App tracks pain management and sleep patterns that may be disrupted by chronic pain.

## New Products: Home Testing and Devices

### **iHearTest**

- Home hearing test kit – provides consumers with the opportunity to assess their hearing
- Determine a ‘Hearing Number’ of 1-5
- Match # to description
- Determine next steps (see next slide)

<https://www.iheardmedical.com/ihear-test/>

## New Products: Home Testing and Devices

### Stick-on UV Exposure Sensors

- **UV Sensor** and **My UV Patch**: battery-free wearable electronic UV exposure meters
- Devices are powered by the user's mobile phone using conventional near-field communication technology.
- App tracks UV exposure and recommends appropriate action such as reapplying sun screen.
- **UV Sensor** can be worn anywhere and tracks exposure to UV light, pollution, humidity, and other environmental factors
- The **My UV Patch** is applied to the skin and uses photosensitive dyes that will alter coloration when exposed to UV radiation.

<https://www.laroche-posay.us/my-uv-patch>

## New Products: Home Testing and Devices

### Wearable Thermometer

- TempTraq<sup>®</sup> is a stick-on thermometer that tracks body temperature.
- The patch continuously measures body temperatures and transmits data to your phone via Bluetooth.
- The patch works for all individuals – kids and adults.
- The flexible patch can be worn for up to 48 hours.

<https://www.temptraq.com/Home>

## New Products: Home Testing and Devices

### **23andMe gained FDA approval late 2018 for a nonprescription pharmacogenomics test:**

- Personal Genome Service Pharmacogenetic Reports
- According to reports from FDA and 23andMe, the test examines 33 different variants for eight different genes that produce drug metabolizing enzymes.
- Covers approximately 50 Rx and OTC medications
- FDA is stating users should NOT make independent decisions with these data.
- Release date to be determined

<https://blog.23andme.com/news/23andme-granted-the-first-and-only-fda-authorization-for-direct-to-consumer-pharmacogenetics-reports/>

## New Legislation

- H.R. 269 passed recently — Over-the-Counter Monograph Safety, Innovation and Reform Act. Aimed at modernizing the OTC monograph process. Goals:
  - Accelerate the process of decision-making
  - Provide FDA with funding and staff for OTC-related work
  - Build an IT infrastructure
  - Improve communication and transparency between regulators and manufacturers by creating a streamlined regulatory path for review of innovations within the OTC monograph system
  - Accommodate changes to ingredients and dosage forms with a submission fee
  - Create a mechanism to encourage investment in the data needed for innovations in self-care for Americans
  - Allow the FDA to quickly address emerging issues due to labeling and safety.
- Needs to be addressed by the Senate

<https://www.congress.gov/bill/116th-congress/house-bill/269>

## New Legislation

**July 17, 2018:** FDA released draft guidance, “[Innovative Approaches for Nonprescription Drug Products](#)”

- Goal: modernize its regulatory framework for nonprescription drugs
- The draft guidance states that product sponsors may use innovative approaches, such as mobile applications or videos, to supplement labeling or provide additional conditions for safe and effective use.
- The draft guidance expands the methods that can be used to demonstrate a product’s safety and effectiveness.

<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM613666.pdf>  
<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613692.htm>



## New Legislation

Two potential ways a product sponsor may demonstrate safety & effectiveness when the drug facts label (DFL) alone is not sufficient to ensure product safety & effectiveness in a nonprescription setting

- 1. Use of technology:** i.e. self-selection test in a mobile application or information displayed on websites. This option would be for labeling (e.g., information leaflets, text or images on a video display, information displayed on websites, & statements or questions in a mobile app), in addition to the DFL.
- 2. More common communications such as information leaflets** contained inside the container for the prescription drug product. This option is implementation of additional conditions (e.g., consumer completion of self-selection test prior to purchase, consumer views text or images explaining appropriate use of the non-prescription drug product and affirms such viewing) so that consumers can appropriately self-select and use the product.

## Recalls

- **Zero Xtreme by Fat Burners Zone: Recall** - Due to Presence of Undeclared Sibutramine
  - <https://www.fda.gov/Safety/Recalls/ucm623503.htm>
- **Homeopathic Aqueous-Based Medicines by Eight and Company, d/b/a Sprayolog: Recall** - Due to Microbial Contamination
  - <https://www.fda.gov/Safety/Recalls/ucm622919.htm>
- **King Bio Issues Voluntary Nationwide Recall of It's Kids and Infant Products** Due to Potential Microbial Contamination
  - <https://www.fda.gov/Safety/Recalls/ucm617945.htm>
- **ThermaCare HeatWraps by Pfizer: Six Lots Recalled** Due to the Potential for Skin Injuries
  - <https://www.fda.gov/Safety/Recalls/ucm626671.htm>

## Recalls

### **March 16, 2018: Alka-Seltzer Plus Products: Recall - Ingredients on Front Sticker May Not Match Product in Carton**

- The ingredients listed on the front sticker of the carton may potentially be different from the ingredients listed on the back of the carton.
- This may lead consumers to ingest a product to which they may have an allergy or anaphylactic reaction, an ingredient which may be contraindicated for their medical condition or they intend to otherwise avoid.
- There may be potential for serious health consequences.

## Recalls

### **April 2018: FDA takes step to protect consumers against dietary supplements containing dangerously high levels of extremely concentrated or pure caffeine**

- FDA took an important step to better protect consumers from the dangers of highly concentrated and pure caffeine products. Highly concentrated and pure caffeine, often sold in bulk packages, have been linked to at least two deaths in otherwise healthy individuals.
- The agency issued a [new guidance](#) to clarify that dietary supplements containing pure or highly concentrated caffeine in powder or liquid forms are considered unlawful when sold in bulk quantities directly to consumers. Given the significant public health concern, this guidance is immediately in effect.

<https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm604485.htm>

## Recalls

### **May 17, 2018: FDA warns companies selling illegal, unapproved kratom products marketed for opioid cessation, pain treatment and other medical uses**

- FDA has issued warning letters to three marketers and distributors of kratom products – [Front Range Kratom](#) of Aurora, Colorado; [Kratom Spot](#) of Irvine, California and [Revibe, Inc.](#), of Kansas City, Missouri – for illegally selling unapproved kratom-containing drug products with unproven claims about their ability to help in the treatment of opioid addiction and withdrawal.
- Kratom is an opioid analogue that may actually contribute to the opioid epidemic and puts patients at risk of serious side effects.
  - Kratom is a tropical evergreen tree native to Southeast Asia
  - FDA has warned about kratom and safety concerns associated with it several times: 44 deaths had been associated with the product

### **May 23, 2018: Oral OTC Benzocaine Teething Products: Drug Safety Communication - Risk of Serious and Potentially Fatal Blood Disorder**

- *Agency urges companies to discontinue teething products, include new warnings for other OTC benzocaine products and revise warnings for approved prescription local anesthetic drugs*
- The products are sold as gels, sprays, ointments, solutions and lozenges under the OTC brand names Anbesol, Baby Orajel, Cepacol, Chloraseptic, Hurricaine, Orabase, Orajel and Topex, as well as store brands and generics.
- Methemoglobinemia is dangerous condition is the result of elevated levels of methemoglobin in the blood and it can lead to death. It causes the amount of oxygen carried through the blood to be greatly reduced.

### **August 27, 2018: Advil recall**

- Pfizer voluntarily recalled one lot of Children's Advil Suspension Bubble Gum Flavored 4 FL OZ Bottle (NDC 0573-0207-30, lot R51129) because of customer complaints that the dosage cup provided is marked in teaspoons and the instructions on the label are described in milliliters (mL).
- Pfizer concluded there is a chance of potential overdose.
- The product was distributed nationwide to wholesalers, distributors and retailers in the United States from May 2018 through June 2018.

[https://www.pfizer.com/sites/default/files/news/Advil%20Paed%20Susp%20Formatted%20%2027%20Aug2018%20\(1\).pdf](https://www.pfizer.com/sites/default/files/news/Advil%20Paed%20Susp%20Formatted%20%2027%20Aug2018%20(1).pdf)

## Recalls

### America Treasure contains hidden drug ingredient

- **November 21, 2018:** The Food and Drug Administration is advising consumers not to purchase or use ***America Treasure***, a product promoted for sexual enhancement. This product was identified during an examination of international mail shipments.
- FDA laboratory analysis confirmed that ***America Treasure*** contains sildenafil, the active ingredient in the FDA-approved prescription drugs Viagra, used to treat erectile dysfunction.

<https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm626395.htm>



## Recalls

- **December 10, 2018:** The Food and Drug Administration is advising consumers not to purchase or use ***On Demand***, a product promoted and sold for sexual enhancement on various websites, including [www.goodlifeondemand.com](http://www.goodlifeondemand.com), and possibly in some retail stores.
- FDA laboratory analysis confirmed that ***On Demand*** contains sildenafil, the active ingredient in the FDA-approved prescription drug Viagra, used to treat erectile dysfunction.

# Recalls

## Public Notifications: January 28, 2019

- GoLean Detox contains hidden drug ingredients: FDA laboratory analysis confirmed that GoLean Detox contains sibutramine and phenolphthalein.  
  
[https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629954.htm?utm\\_campaign=CDER%20New%2001%2F29%2F2019&utm\\_medium=email&utm\\_source=Eloqua&elqTrackId=845abd13165c43e780e48a9907c70995&elq=5fe4e35209e8424da38ddbdeae9c9a&elqaid=6545&elqat=1&elqCampaignId=5350](https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629954.htm?utm_campaign=CDER%20New%2001%2F29%2F2019&utm_medium=email&utm_source=Eloqua&elqTrackId=845abd13165c43e780e48a9907c70995&elq=5fe4e35209e8424da38ddbdeae9c9a&elqaid=6545&elqat=1&elqCampaignId=5350)
- Ultra Fit contains hidden drug ingredients: FDA laboratory analysis confirmed that Ultra Fit contains sibutramine and N-desmethylsibutramine.  
  
[https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629903.htm?utm\\_campaign=CDER%20New%2001%2F29%2F2019&utm\\_medium=email&utm\\_source=Eloqua&elqTrackId=bed4ab2f2f83439d899a34a7a4860170&elq=5fe4e35209e8424da38ddbdeae9c9a&elqaid=6545&elqat=1&elqCampaignId=5350](https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629903.htm?utm_campaign=CDER%20New%2001%2F29%2F2019&utm_medium=email&utm_source=Eloqua&elqTrackId=bed4ab2f2f83439d899a34a7a4860170&elq=5fe4e35209e8424da38ddbdeae9c9a&elqaid=6545&elqat=1&elqCampaignId=5350)
- Red Stallion Extra Strong contains hidden drug ingredient: FDA laboratory analysis confirmed that Red Stallion Extra Strong contains tadalafil.  
  
[https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629900.htm?utm\\_campaign=CDER%20New%2001%2F29%2F2019&utm\\_medium=email&utm\\_source=Eloqua&elqTrackId=6c08db329abd4fafafdb83fb215d222b&elq=5fe4e35209e8424da38ddbdeae9c9a&elqaid=6545&elqat=1&elqCampaignId=5350](https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629900.htm?utm_campaign=CDER%20New%2001%2F29%2F2019&utm_medium=email&utm_source=Eloqua&elqTrackId=6c08db329abd4fafafdb83fb215d222b&elq=5fe4e35209e8424da38ddbdeae9c9a&elqaid=6545&elqat=1&elqCampaignId=5350)
- Natural V=GRA contains hidden drug ingredients: FDA laboratory analysis confirmed that Natural V=GRA contains sildenafil and tadalafil.  
  
[https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629897.htm?utm\\_campaign=CDER%20New%2001%2F29%2F2019&utm\\_medium=email&utm\\_source=Eloqua&elqTrackId=296bcab5f3dc49b2a86b9e7bf22b4f64&elq=5fe4e35209e8424da38ddbdeae9c9a&elqaid=6545&elqat=1&elqCampaignId=5350](https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629897.htm?utm_campaign=CDER%20New%2001%2F29%2F2019&utm_medium=email&utm_source=Eloqua&elqTrackId=296bcab5f3dc49b2a86b9e7bf22b4f64&elq=5fe4e35209e8424da38ddbdeae9c9a&elqaid=6545&elqat=1&elqCampaignId=5350)
- Yong Gang contains hidden drug ingredients: FDA laboratory analysis confirmed that Yong Gang contains sildenafil and tadalafil.  
  
[https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629894.htm?utm\\_campaign=CDER%20New%2001%2F29%2F2019&utm\\_medium=email&utm\\_source=Eloqua&elqTrackId=329575bd10774d9085bcc2dc268775f5&elq=5fe4e35209e8424da38ddbdeae9c9a&elqaid=6545&elqat=1&elqCampaignId=5350](https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629894.htm?utm_campaign=CDER%20New%2001%2F29%2F2019&utm_medium=email&utm_source=Eloqua&elqTrackId=329575bd10774d9085bcc2dc268775f5&elq=5fe4e35209e8424da38ddbdeae9c9a&elqaid=6545&elqat=1&elqCampaignId=5350)
- Golden Ant contains hidden drug ingredient: FDA laboratory analysis confirmed that Golden Ant contains sildenafil.  
  
[https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629891.htm?utm\\_campaign=CDER%20New%2001%2F29%2F2019&utm\\_medium=email&utm\\_source=Eloqua&elqTrackId=ae547891a42c435c95d068141764a641&elq=5fe4e35209e8424da38ddbdeae9c9a&elqaid=6545&elqat=1&elqCampaignId=5350](https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629891.htm?utm_campaign=CDER%20New%2001%2F29%2F2019&utm_medium=email&utm_source=Eloqua&elqTrackId=ae547891a42c435c95d068141764a641&elq=5fe4e35209e8424da38ddbdeae9c9a&elqaid=6545&elqat=1&elqCampaignId=5350)

# Recalls

- **Instinct Best Sexual Enjoyment contains hidden drug ingredient:** FDA laboratory analysis confirmed that Instinct Best Sexual Enjoyment contains sildenafil,  
[https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629888.htm?utm\\_campaign=CDER%20New%2001%2F29%2F2019&utm\\_medium=email&utm\\_source=Eloqua&elqTrackId=1c9f0a5c6bf9409eb81c365dcca8d06d&elq=5fe4e35209e8424da38ddbdeaeba9c9a&elqaid=6545&elqat=1&elqCampaignId=5350](https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629888.htm?utm_campaign=CDER%20New%2001%2F29%2F2019&utm_medium=email&utm_source=Eloqua&elqTrackId=1c9f0a5c6bf9409eb81c365dcca8d06d&elq=5fe4e35209e8424da38ddbdeaeba9c9a&elqaid=6545&elqat=1&elqCampaignId=5350)
- **Black King Kong contains hidden drug ingredient:** FDA laboratory analysis confirmed that Black King Kong contains sildenafil,  
[https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm436002.htm?utm\\_campaign=CDER%20New%2001%2F29%2F2019&utm\\_medium=email&utm\\_source=Eloqua&elqTrackId=148616ef46ea4c04b869f511c0b5b2a5&elq=5fe4e35209e8424da38ddbdeaeba9c9a&elqaid=6545&elqat=1&elqCampaignId=5350](https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm436002.htm?utm_campaign=CDER%20New%2001%2F29%2F2019&utm_medium=email&utm_source=Eloqua&elqTrackId=148616ef46ea4c04b869f511c0b5b2a5&elq=5fe4e35209e8424da38ddbdeaeba9c9a&elqaid=6545&elqat=1&elqCampaignId=5350)
- **"1 Day Diet" Contains Hidden Drug Ingredient:** FDA laboratory analysis confirmed that "1 Day Diet" contains sibutramine.  
[https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm376062.htm?utm\\_campaign=CDER%20New%2001%2F29%2F2019&utm\\_medium=email&utm\\_source=Eloqua&elqTrackId=bde32623727b4c2397ac78eca35af3a7&elq=5fe4e35209e8424da38ddbdeaeba9c9a&elqaid=6545&elqat=1&elqCampaignId=5350](https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm376062.htm?utm_campaign=CDER%20New%2001%2F29%2F2019&utm_medium=email&utm_source=Eloqua&elqTrackId=bde32623727b4c2397ac78eca35af3a7&elq=5fe4e35209e8424da38ddbdeaeba9c9a&elqaid=6545&elqat=1&elqCampaignId=5350)
- **Slim Bio Capsules contain hidden drug ingredients:** FDA laboratory analysis confirmed that Slim Bio Capsules contain sibutramine, N-desmethyilsibutramine, sildenafil, tadalafil, benproperine and diphenhydramine.  
[https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629874.htm?utm\\_campaign=CDER%20New%2001%2F29%2F2019&utm\\_medium=email&utm\\_source=Eloqua&elqTrackId=65d3c2cc3d594487b26ab8180a5193d7&elq=5fe4e35209e8424da38ddbdeaeba9c9a&elqaid=6545&elqat=1&elqCampaignId=5350](https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629874.htm?utm_campaign=CDER%20New%2001%2F29%2F2019&utm_medium=email&utm_source=Eloqua&elqTrackId=65d3c2cc3d594487b26ab8180a5193d7&elq=5fe4e35209e8424da38ddbdeaeba9c9a&elqaid=6545&elqat=1&elqCampaignId=5350)
- **Slimmer Extreme Thermogenic Formula contains hidden drug ingredients:** FDA laboratory analysis confirmed that Slimmer Extreme Thermogenic Formula contains sibutramine and phenolphthalein  
[https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629879.htm?utm\\_campaign=CDER%20New%2001%2F29%2F2019&utm\\_medium=email&utm\\_source=Eloqua&elqTrackId=5da331d09b0d474b9378083f99281ce2&elq=5fe4e35209e8424da38ddbdeaeba9c9a&elqaid=6545&elqat=1&elqCampaignId=5350](https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629879.htm?utm_campaign=CDER%20New%2001%2F29%2F2019&utm_medium=email&utm_source=Eloqua&elqTrackId=5da331d09b0d474b9378083f99281ce2&elq=5fe4e35209e8424da38ddbdeaeba9c9a&elqaid=6545&elqat=1&elqCampaignId=5350)
- **Nectar Del Amor contains hidden drug ingredient:** FDA laboratory analysis confirmed that Nectar Del Amor contains sildenafil  
[https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629882.htm?utm\\_campaign=CDER%20New%2001%2F29%2F2019&utm\\_medium=email&utm\\_source=Eloqua&elqTrackId=7c9fcd5757c94924b17052bedd0e8b3&elq=5fe4e35209e8424da38ddbdeaeba9c9a&elqaid=6545&elqat=1&elqCampaignId=5350](https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm629882.htm?utm_campaign=CDER%20New%2001%2F29%2F2019&utm_medium=email&utm_source=Eloqua&elqTrackId=7c9fcd5757c94924b17052bedd0e8b3&elq=5fe4e35209e8424da38ddbdeaeba9c9a&elqaid=6545&elqat=1&elqCampaignId=5350)

## Recalls

**January 29, 2019**

- **Tris Pharma, Inc Expands Its Voluntary Nationwide Retail Recall of Ibuprofen Oral Suspension Drops, USP, 50 mg per 1.25 mL, Due to Higher Concentration of Ibuprofen**
- Expanded the scope of its November 2018 recall by adding three (3) additional lots of **Ibuprofen Oral Suspension Drops, USP, 50 mg per 1.25 mL**, to the retail (pharmacy) level.
- Concentration could be up to 10% higher than labeled

<https://www.fda.gov/Safety/Recalls/ucm627780.htm>

[https://www.fda.gov/Safety/Recalls/ucm627780.htm?utm\\_campaign=Tris%20Pharma%20Issues%20Voluntary%20Nationwide%20Recall%20of%20Infants%E2%80%99%20Ibuprofen%20Concentrated%20Oral%20Suspension&utm\\_medium=email&utm\\_source=Eloqua](https://www.fda.gov/Safety/Recalls/ucm627780.htm?utm_campaign=Tris%20Pharma%20Issues%20Voluntary%20Nationwide%20Recall%20of%20Infants%E2%80%99%20Ibuprofen%20Concentrated%20Oral%20Suspension&utm_medium=email&utm_source=Eloqua)

## Recalls

### January 29, 2019

- **Nature's Rx Issues Voluntary Nationwide Recall of Silver Bullet 10x to Undeclared PDE-5 Inhibitors in the Product**
- Nature's Rx is voluntarily recalling quantity lots of Silver Bullet 10x, description of dosage form to the hospital, retail or consumer level.
- The product was found to contain undeclared sildenafil and tadalafil, the active ingredient in Viagra and Cialis respectively.

## Recalls

### **February 1, 2019: Home-use test strips used with device to monitor blood thinner warfarin, not authorized for sale in U.S.**

- Terrific Care/Medex Supply LLC issued a voluntary recall of certain Roche Diagnostics test strip lots used with CoaguChek test meter devices.
- [Class I recall](#), the most serious type of recall, which means use of these devices may cause serious injuries or death.
- This recall is related to the November 2018 [Roche Diagnostics Recall](#), the manufacturer of CoaguChek meters and test strips.
- Strips were not labeled or authorized for sale in the U.S. and were only distributed by Roche Diagnostics outside the country.
- Distributor purchased the Roche test strips from an unknown source and imported and sold them in the U.S.

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm630408.htm>

## Innovative Approaches for Nonprescription Drug Products

- **July 2018:** FDA published a draft guidance for industry entitled “Innovative Approaches for Nonprescription Drug Products.”
- Describes two innovative approaches for demonstrating safety and effectiveness for a nonprescription drug product in cases where the drug facts labeling (DFL) alone is not sufficient:
  1. The development of labeling in addition to the DFL
  2. Implementation of additional conditions so that consumers appropriately self-select and use the product.
- Comments were due Sept 17, 2018
- Remember NSURE (the Nonprescription Safe Use Regulatory Expansion initiative) – expanded availability of medications (OTC?) to manage certain chronic diseases? Is this another step in that direction? We’ll see...

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613692.htm>

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## **III INNOVATIVE APPROACHES FOR NONPRESCRIPTION DRUG PRODUCTS**

### **A. Labeling in Addition to the DFL for Nonprescription Drug Products**

In addition to labeling created to satisfy the DFL requirements,<sup>5</sup> FDA may approve additional labeling for nonprescription drug products (see section 505(d) of the FD&C Act (21 U.S.C. 355(d)). Examples of nonprescription drug product labeling the Agency may consider approving in addition to the DFL include, but are not limited to, the following:

- Information leaflets or other documents contained inside the carton or container for the nonprescription drug product
- Text or images on a video display, including interactive displays for consumers to review
- Information displayed on websites
- Statements or questions in a mobile application

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613692.htm>



## Innovative Approaches for Nonprescription Drug Products

### **B. Nonprescription Drug Products With Additional Conditions for Safe and Effective Use**

Applicants may consider proposing one or more additional conditions that consumers must fulfill to ensure that the drug product is safe and effective for nonprescription use, when labeling alone is not sufficient for this purpose.

Examples of additional conditions for safe and effective use that the Agency may consider, particularly with regard to appropriate self-selection and actual use, include, but are not limited to, the following:

- Prior to purchase, the consumer is required to respond to a set of questions on a self-selection test in a mobile application, and the outcome of the self-selection test affirmatively indicates that the consumer is an appropriate candidate to use the nonprescription drug product.
- Prior to purchase, the consumer is required to view and affirm that they viewed text or images in a video that describes how to appropriately use the nonprescription drug product.

As part of the development process for a nonprescription drug product for which an additional condition for nonprescription use will be proposed, applicants should consider how to ensure proper implementation of any additional condition necessary for safe and effective use.

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613692.htm>

## Assessment Questions

1. All of the following are key points to share with a consumer interested in buying Primatene Mist EXCEPT:
  - A. Talk with your pharmacist or doctor before using if you are taking a medicine for allergies, such as pseudoephedrine.
  - B. Do not use unless your doctor said you have asthma
  - C. It is important to use this every 4 hours for maximal relief
  - D. Talk with your pharmacist or doctor before using if you are taking a medicine for depression

## Assessment Questions

2. Which of the following is the active ingredient in ZzzQuil PureZZZs?
- A. Diphenhydramine
  - B. Melatonin
  - C. Doxylamine
  - D. Passion Flower

## Assessment Questions

3. Drkids offers products that are:
- A. Flavored to be compatible with all kids' tastes
  - B. Packaged with a dosing spoon and dosing syringe
  - C. Homeopathic to eliminate risk
  - D. Single-use vials with premeasured doses

## Assessment Questions

4. Kratom is an ingredient in many recalled products because it is thought to have which property?
- A. Muscle-building
  - B. Sexual enhancement
  - C. Opioid cessation/addiction
  - D. Weight loss

# Your Annual OTC Update

*Thank you  
Questions?*