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FDA speaks out

THE US Food and Drug Administration has issued warning letters to Johnson & Johnson, the CVS Corporation and the Walgreen Company, regarding unproven claims about their respective mouth wash products.

According to the agency the companies' Listerine Total Care Anticavity Mouthwash (J&J), CVS Complete Care Anticavity Mouthwash (CVS) and Walgreen Mouth Rinse Full Action (Walgreen), all make claims that their products either remove plaque above the gum line, promote healthy gums or prevent gum disease.

In actuality the FDA says that whilst the products' active ingredient sodium fluoride is effective in preventing cavities, no evidence has been offered up to show that it removes plaque or prevents gum disease.

The three companies now have 15 days to "take appropriate action" to correct the violations.

MEANWHILE the FDA has also issued its final ruling on what safety information must be reported during clinical trials of investigational drugs and biologics.

According to the rule within 15 days of becoming aware of an occurrence companies must file a report with the FDA that includes: findings that suggest a significant risk to participants and serious suspected adverse reactions that occur at a higher rate than expected.

The report must also include info on serious adverse events from bioavailability studies which determine what percentage and at what rate drug is absorbed by the bloodstream and bioequivalence studies which determine whether a generic drug has the same bioavailability as the brand name drug.

Sigma takes its medicine

SIGMA Pharmaceuticals's new managing director Mark Hooper has cleared the decks with the company's half year result, with one-off inventory write-offs and restructuring costs amounting to \$24.7m, and devaluing the Pharmaceuticals division by \$220 million (**PD** breaking news).

The writedowns have seen Sigma report a net loss after tax of \$218.5 million - compared to a \$32.2m profit for the same period last year.

The impairment of the Pharmaceutical division is due to its proposed \$900m sale to Aspen Pharamcare, which is for a price lower than the carrying value in the Sigma accounts.

The company said it had continued its negotiations with lenders in respect to the breach of banking covenants, with "certain one off adjustments" meaning Sigma's finances are secure.

Sigma confirmed that on 30 Aug it repaid \$40m of its syndicated bank loan liability, with the payment funded via working capital.

As far as the outlook is concerned, Sigma said it's maintaining previous guidance of "underlying EBIT" of between \$140m and \$150m for the year to 31 Jan 2011, subject to the successful sale of the Pharmaceuticals division and "assuming a continuation of a normal operating environment".

The healthcare division's sales revenue was up 8% to \$1.34b, but earnings before interest and tax was down 17% to \$28.6m.

"Growth in sales revenue was due to PBS growth and strong support from our customers...we have also been working with these customers to reduce the extended settlement

terms to a more sustainable basis that reflects current credit conditions," the company said.

For the pharmaceuticals business revenue growth was weaker, up just 1.8% to \$275m, and an underlying EBIT of \$40.2m before writedowns amounting to \$238m in total.

Sigma said there were lower sales for its generics and consumer business units, while continued aggressive discounting in the generics market also reduced profit.

"Future marketing initiatives within the consumer business are expected to raise the level of brand awareness within our direct grocery channel," the company said.

Hopper said the company's challenges "are well documented and of disappointment to the Board, management and shareholders.

"While there is much more to do to reconfigure the business for a stronger future, in the few weeks since I started as MD I have seen encouraging signs of stability returning to the business," he said.

Treatment via text

PATIENTS who received educational information on their condition, along with medication reminders via SMS text messaging had improved rates of medication adherence, according to a new study conducted by the US Centre for Connected Health.

The study involved 25 teenagers and adults who suffered from atopic dermatitis, and who admitted to often forgetting their medication (92%) and who stopped taking meds when their condition improved (88%).

Published in the current Dermatology Research and Practice journal, the study involved an initial consult with patients, followed by daily text messages providing condition information and reminding them to continue their treatment, followed by a final consultation at the seventh week.

According to researchers, at the end of the study 72% of participants reported improved adherence and 68% reported an improvement in their self-car skin routine.

WIN AN ORGANIC HAND WASH



Certified Organics at a low price for FAST sell through!

This week **Pharmacy Daily** is giving readers the chance to win an Aloe Leaf Hand Wash from **Designer Brands NEW Organic Collection**.

Designer Brands Organics provides intense

moisturising protection for hair and skin, leaving it soft and supple for complete head to toe hydration. With the launch of Designer Brands Organics, certified organic skin care no longer means having to pay the price for purity. This paraben-free, urea-free, SLS-free, artificial colour-free range is certified organic, dermatologist tested and is biodegradable. Good for you and the planet!

Based on the healing and nurturing power of organic Aloe Leaf Juice, this is beauty without boundaries when it comes to skin and hair loving benefits and affordability.

For your chance to win, simply send through the correct answer to the daily question below:

What main ingredient is used in all the products?

Email your answer to: comp@pharmacydaily.com.au

The first correct entry received will win!

Hint: Visit www.dbcosmetics.com.au

Congratulations to yesterday's lucky winner: **Kate Wharton** from **Pulse Pharmacy Robertson Drive**.

Pharmacy Daily Pharmacy Job of the Day!

Jobs4Careers is Australia's leading source for pharmacy jobs ... click here to find out more and see the Pharmacy Daily Job of the Day ...

jobs4careers.com.au

Dementia support

THE Department of Health and Ageing is trialling a new program to support people caring for dementia sufferers.

The 'Carer's Care' program includes a self-help DVD, tip sheets and web support and is currently being trialled in Tasmania under Home and Community Care funding.

"In our ageing society, it's important that carers receive full support," said the Minister for Mental Health and Ageing Mark Butler.

For info see www.health.gov.au.

Just one click away from keeping up to date with all the breaking news as it comes to hand...



Health, Beauty and New Products

Welcome to our weekly feature with all the latest health, beauty and new products for pharmacy!

Suppliers wanting to promote products in this feature should email advertising@pharmacydaily.com.au.

Chrissie gift sets

Frostbland have released four affordable female fragrance gift lines in the lead up to the festive season. Each of the four lines Panache, Tweed, White Satin and Lace includes a Duo Set (15ml spray and perfumed body fragrance), a 30ml (or 25ml for Tweed and White Satin) Perfume and Body Spray Set and a 3 Piece Deluxe Set (30ml perfume, perfumed talcum powder 100g and perfumed soap 100g). Panache is traditional floral and musk scent, designed to invoke the 1970's Charlie's Angels era, whilst Tweed is similar to Red Door, White Satin is a "sweet and warm" scent which mingles floral notes with green and musk, and Lace includes green, floral and bergamot notes with rose, lilly, geranium, amber, musk and vanilla.

RRP: \$14.95 (Duo Set), \$19.95 (Perfume and Body Spray Set), \$24.95 (3 Piece Set)
Stockist: 02 8709 8800



Daisy Pop Art

Marc Jacobs has released a new collectors limited edition pop art collectible bottle, creatively titled: The Daisy Marc Jacobs Pop Art Edition. Inside the funky bottle, the perfume is a richer interpretation of the edu de toilette Daisy, and features fresh wild strawberry notes, as well as a combination of violet, gardenia and jasmine. Finishing off the scent are accords of birch and cedarwood.

RRP: \$140ml
Stockist: www.daisymarcjacobs.com.

Instant skin perfection

Clarins has launched an Instant Light Brush-On Perfector which is designed to conceal skin imperfections and brighten fatigued skin. Applied via a click of its pen applicator and a few sweeps of the attached brush, the Perfector formulation is lightweight and melts into the skin. Key ingredients include hyaluronic acid to hydrate skin, oat sugars to firm skin tone and Clairs' 'Light Optimising Complex' which acts to reflect light and in doing so reduce the appearance of fine lines and dark circles. The Perfector can also be applied to the cheek and brow bones to illuminate and create definition.

RRP: \$59 (65ml)
Stockist: 02 9663 4277



Develop a sunless spring tan

Hissyfit has launched a new body bronze self tanning lotion, which it claims provides users with a natural-looking tan without streaking. Because self tanning product ingredients tend to dry out skin Hissyfit has infused its formulation with aloe vera to provide skin with a moisture boost, as well as Vitamins B, C and E to nourish and protect it.

RRP: \$29.95
Stockist: 1800 630 056

Grow your own pure skin

Certified organic, Grown's new Deep Purifying Facial Masque is based on white clay which acts to draw impurities trapped in the skin to the surface, and absorb excess oil. The formulation is also infused with cranberry seed which provides a boost of antioxidant rich gamma-tocotrienols and astaxanthin, as well as ginkgo and centella for their wealth of bioflavonoids and antioxidants and wheatgerm which offers Vitamin A, E and D as well as fatty acids.

RRP: \$39
Stockist: 02 9477 6900



DISPENSARY CORNER

LOOKING for the perfect nap spot. A US man, Bennett Turner, is facing criminal charges after police caught him breaking into a county pharmacy.

According to reports Turner entered the location by taking apart the pharmacy's vent and climbing into the attic.

Responding to a silent alarm at the pharmacy, officers busted Turner after he was found hiding in a locked closet in the store's attic.

Police allege it was Turner's intent to rob the pharmacy as he was in possession of burglary tools, however Turner has defended himself, saying he just wanted a place to have a nap.

Turner also told police that he often naps in the store's attic, however police have rebuffed that claim, saying that this is the first time they have responded to the motion sensitive alarm.

BANDAIDS needed!

Four Australian Institute of Sport students 'The Pinkettes' have become the fastest quartet in a relay race run whilst wearing stiletto heels.

The race, held this week in Canberra, attracted 100 girls from across the nation, all vying for the top spot across the 80 metre course.

The group, Brittney McGlone, Laura Juliff, Casey Hodges and Jessica Penny are now planning to spend their \$10,000 prize money on a holiday to Phuket.

Race sponsors also donated a \$20,000 cheque to the National Breast Cancer Foundation.

And ladies: According to McGlone the key to stiletto running is to race on your toes!

THAT'S one tired musician.

While the rest of us lazed about last weekend, German muso, Vicente Patiz, spent his time travelling to eight countries and playing gigs in 24 hours (a world record), and then recovering!

During his whirlwind tour Patiz travelled to Germany, Belgium, the Netherlands, Luxembourg, France, Switzerland, Liechtenstein and Austria.