



## Rx TWO PHARMACY SERVICES, INC. MEDICATION NEWSLETTER

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### Medicare & CMS News

CMS has entirely revised the Unnecessary Medication Guidelines (F329) including clarifications of several aspects of medication management and a new medication table page that includes medications that are problematic to the nursing home population. For Pharmacy Services, regulatory guidance presently at Tags F425-431 have been combined into three remaining tags: F425 Pharmacy Services, F425 Drug Regimen Review, and F431 Labeling and Storage of Drugs and Biologicals. The new guidance speaks to the provision of pharmaceutical services for the entire distribution system, from ordering and acquisition to administration and disposal of medications to assure a safe system for each resident. These new guidelines are scheduled to be effective December 18, 2006. The full text of these documents can be accessed on the ASCP Web site at: <http://www.ascp.com/som>

### New FDA Approved Medications, Warnings, Indications, Formulations and News:

The FDA has approved a new use of the anti-seizure medicine Lamictal® (lamotrigine) Tablets for the treatment of one of the most serious forms of epilepsy -- Primary Generalized Tonic-Clonic (PGTC) seizures, also known as "grand mal" seizures. With this new indication, Lamictal can now be used as add-on therapy to treat PGTC seizures in children aged 2 and older as well as adults. This new use marks the fifth FDA approval for Lamictal in epilepsy, making it one of the few antiepileptic drugs with established efficacy in a broad spectrum of seizure types, including partial and generalized seizures. Lamictal is also approved as maintenance therapy for adults with bipolar I disorder.

Cephalon, Inc. has received approval from the FDA to market Fentora (fentanyl buccal tablet) [C-II] for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Fentora is the first and only buccal tablet approved for this indication. The sugar-free Fentora tablet is placed between the upper cheek and gum above a rear molar tooth. When it comes into contact with saliva, Fentora's delivery system generates a reaction leading to the release of carbon dioxide. It is believed that transient pH changes accompanying this reaction may optimize how well the tablet dissolves and how quickly the medicine passes across the buccal mucosa. Cephalon will manufacture Fentora in five dosage strengths: 100, 200, 400, 600, and 800 micrograms (mcg). Fentora will be packaged in cartons containing twenty-eight tablets (seven child-resistant blister cards with four tablets in each card).

The FDA is notifying consumers and health care professionals that the coadministration of ibuprofen and aspirin for pain relief may interfere with aspirin's cardiovascular benefits. Ibuprofen can interfere with the antiplatelet effect of low-dose aspirin (81 mg/day), causing it to be less effective when used for cardioprotection and stroke prevention. Although ibuprofen and aspirin can be taken together, the FDA recommends that patients taking immediate release low-dose aspirin (not enteric coated) and ibuprofen 400mg should take the ibuprofen at least 30 minutes after aspirin ingestion, or at least 8 hours before aspirin ingestion to avoid any potential interaction.

Influenza vaccine manufacturers are projecting that approximately 100 million doses of influenza vaccine will be available in the U.S. for use during the 2006-07 influenza season. This amount represents approximately 16% more doses than were available for the 2005-06 season. Below is a table listing the various influenza vaccine preparations:

Manufacturer/Vaccine	Formulation	Age indication
Sanofi Pasteur  Fluzone®, Inactivated TIV	Multi-dose vial*	≥6 months
	Single-dose pre-filled 0.5 mL syringe or vial	≥ 36 months
	Single-dose pre-filled 0.25 mL syringe	6-35 months
Novartis Vaccine (formerly Chiron Corporation)  Fluvirin™ Inactivated TIV	Multi-dose vial*	≥ 4 years
	Single-dose 0.5 mL syringe	≥ 4 years
GlaxoSmithKline, Inc  Fluarix™ Inactivated TIV	Single-dose pre-filled syringe 0.5 mL	≥ 18 years
MedImmune Vaccines, Inc  FluMist™ LAIV	Single-dose sprayer	Healthy persons  5-49 years

\*Contains Thimerosal preservative

The FDA has approved the use of clopidogrel bisulfate (Plavix) for patients who have had acute ST-segment elevation myocardial infarction (STEMI) who are not going to have angioplasty to repair their affected coronary artery. STEMI is a severe acute heart attack in which a coronary artery is generally blocked completely. About half a million Americans

have this type of heart attack annually. Clopidogrel prevents subsequent blockage in the already-damaged heart vessel, which could lead to more heart attacks, stroke, and possibly death. Both the COMMIT and CLARITY studies support the effectiveness of Plavix in treating STEMI heart attack patients. Serious side effects of Plavix include bleeding and, rarely, low white blood cell counts or thrombotic thrombocytopenic purpura (low platelet counts with spontaneous bleeding and clotting).

Valeant Pharmaceuticals has launched Zelapar (Selegiline HCL) Orally Disintegrating Tablets. Zelapar is the first Parkinson's disease treatment to use a novel oral delivery system called Zydis Technology, which allows the tablets to dissolve in the mouth within seconds to deliver active drug at a lower dose. Zelapar is a selective monoamine oxidase inhibitor approved by the FDA as a once daily adjunct therapy for patients with Parkinson's disease being treated with levodopa/carbidopa.

Cubicin (daptomycin) is now indicated for treating Staphylococcus aureus bacteremia, including right-sided endocarditis caused by strains of this organism that are resistant or sensitive to methicillin.

#### Generic Drug Approvals:

- Clopidogrel (Plavix) 75mg tabs
- Transmucosal Fentanyl Citrate (Actiq)
- Ciprofloxacin IV (Cipro) 200mg, 400mg
- Meloxicam (Mobic) 7.5mg, 15mg

*Rx Two Pharmacy Services, Inc. was formed by a group of dedicated and seasoned LTC pharmacy professionals with the goal of providing comprehensive pharmacy services for our contracted nursing centers and their residents by utilizing state of the art computer technology and good old fashioned hard work.*

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