FDA to Allow Radio Frequency Tags in Drug Labels

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ROCKVILLE, MD. — The Food and Drug Administration has reassured pharmaceutical companies that they can use radio frequency identification technology in product packaging without running afoul of agency rules, at least through 2007.

"Today's actions were designed with one goal in mind: to increase the safety of medications consumers receive by creating the capacity to track a drug from the manufacturer all the way to the pharmacy," acting FDA Commissioner Lester M. Crawford, D.V.M., Ph.D., said in a press briefing sponsored by the FDA.

At the same time, Purdue Pharma LP, Pfizer, and GlaxoSmithKline all said they soon would begin using radio frequency identification (RFID) technology in packaging for some of their products.

RFID is slowly being adopted by retailers to track inventory. Tags that contain in-

formation about the product can be embedded into pallets or labels and then read by wireless scanners.

The new FDA policy should convince drug makers that they can safely use RFID tags, said Paul Rudolf, M.D., FDA senior adviser for medical and health policy. Between now and 2007, companies can experiment with RFID without fear of sanctions, he said. FDA officials said that until now, pharmaceutical manufacturers have hesitated to incorporate the tags into their

products out of concern that the agency—which by law must approve everything about a drug's label—might then consider a drug mislabeled.

The agency believes RFID technology could also deter counterfeiting. A tag could be embedded into a large pill bottle or block of packages at the factory, with information on the drug's potency, its destination, and other important data. Using special scanners and software, the distributor and the pharmacy will then be able to read the tag. RFID will help create an "electronic pedigree," allowing manufacturers, distributors, and pharmacists to verify the drug's le-

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g i t i m a c y, according to the FDA.

"The entire chain of custody can be followed," said Dr. Rudolf.

"The threat [of counterfeiting] is real and needs to be addressed in a real and strong way," said William Hubbard,

FDA's associate commissioner for policy and planning, who hastened to add that the "drug supply in this country is very safe now."

There have been instances, however, when impurities have been found in counterfeit pharmaceuticals, and in one case, where an injectable drug was filled with "nothing more than tap water," said Thomas McGinnis, Pharm.D., FDA's director of pharmacy affairs.

At press time, Purdue Pharma, which has weathered difficulties with theft and diversion of its pain killer OxyContin (oxycodone), said it would begin sending RFID-tagged 100-tablet bottles to Wal-Mart and H.D. Smith Wholesale Drug Co. The company is also donating 100 handheld scanners to law enforcement groups around the country and using special color-shifting ink on the label that will let pharmacists know that the bottle came from Purdue.

GlaxoSmithKline said it would start using RFID tags on at least one of its products deemed to be susceptible to counterfeiting in the next year-and-a-half. Those products include Retrovir (zidovudine), Combivir (lamivudine/zidovudine), Epivir (lamivudine), Trizivir (abacavir, lamivudine, and zidovudine), Ziagen (abacavir), and Zofran (ondansetron), according to the company.

Pfizer said that it expected to have RFID tags for Viagra (sildenafil) by the end of next year. Viagra is one of the most counterfeited medicines in the United States, the company said.

Dr. Rudolf added that he did not expect the cost of anticounterfeiting technology to be passed on to consumers, as it would save money by curbing counterfeiting.

A recent report by the Healthcare Distribution Management Association's Healthcare Foundation seems to back up that assertion: The report estimated that \$200 million to \$400 million could be saved each year by decreasing drug counterfeiting.

F SUMMARY Of PRESCRIBING INFORMATION

MIDICATIONS AND USAGE: Bipolar Mania: SERDOUEL is indicated for the short-term treatment of acute manic episodes associated with bipolar if disorder, as either monotherapy or adjunct therapy to lithium or divaleptore. The efficacy of SERDOUEL in acute bipolar mania was established in two 3-week monotherapy trais and one 3-week adjunct therapy trail of bipolar platefiles instally hissplated for up to 7 days for acute mania. Effectiveness for more than 3 weeks has not been systematically evaluated in clinical trails. Therefore, the physician who elects to use SERDOUEL for setted periodically re-evaluated the long-term firsts and benefits of the drug for the individual patient. Schizophrenia: SERDOUEL is indicated for the treatment of schizophrenia. The effects of the schizophrenia was established in short-term (Fewel) countrolled trails of schizophrenia repaired in a schizophrenia was established in short-term (Seets) to use of the schizophrenia schizophrenia was established in short-term (Seets) to use SERDOUEL in thorse the physical way to be este to use SERDOUEL for extended periods should evaluated in controlled trials. Therefore, the physical way to because the schizophrenia was established in short-term (Seets) to use SERDOUEL for extended periods should evaluated in controlled trials. Therefore, the physical way to seet to use SERDOUEL for extended periods should extend the schizophrenia was established to short-term (Seets) to use SERDOUEL for extended periods should extend the schizophrenia was established to short-term (Seets) and t

CONTRAINDICATIONS: SEROQUEL is contraindicated in individuals with a known hypersensitivity to this medication or any of its incredients.

WARNINGS: Neurolepic Malignant Syndrome (MISS) A potentially fatal symptom complex sometimes referred to a Reurolepic Malignant Syndrome (MISS) has been reported in association with administration of antiposychotic drugs, including SEROOUEL. Flarer cases of MISS have been reported with SEROOUEL. Clinical manifestations of MISS are hyperpressy, muscle rigidity, altered mental status, and evidence of automomic instability (frrequist pulse or blood pressure, techycardia, disphoresis, and cardiac dystrythmia). Additional signs may include elevated oresembly proposed in the prosphorisms (make mysophorisma (indexhoryloss)) and carde ernel failure. The dispositor evaluation of patients with this syndrome is complicated. In arriving at a diagnosis, it is important to exclude cases where the clinical presentation includes both serious medical limites (e.g., permention, systemic infection, etc.) and untreated or inadequably treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential darguent and the presentation includes the medical articolorisms of the management of MIMS should include: 1) immediate descontinuation of artispsychotic drugs and other diagnost extraction in concurrent therapy? Juntensive symptomiate returnment and artispsychotic drugs and other agreement about specific pharmacological teratment requires or MIMS. In a patient and recovery from MIMS, the patient teratment and requires a available. There is no general patient symbol activity of the produces of the symbol patients of the patient symbol activity of the produces of the symbol patients of the patient symbol activity of the symbol patients which are carefully monitored similar to the syntonic requires an artispsychotic drugs. Altonomy the prevalence of the syntonic movements may develop in patients the advantage of the patient symbol activity of the exist of the syntonic may be a fine the patient of the patient and produces and the licentification of the symbol patients of the symbol patients of the patient

ably effecting its or-admencip antaponiet properties. Sprucipe was reported in 1%; (22567) and the control drugs. SEROUEL should be used with particular caution in patients with known cardiovascular disease (history of mycardial infaction or schemic heart disease, heart failure or conduction abnormalities, cerebrovascular disease or conditions which would predispose patients to hypotension (dehydration, hypovolemia and treatment with anti-intal does to 25 mg bid. If hypotension occurs during flutation to the target dose, a return to the previous dose in the traditions which is appropriate, Cataracts. The development of cataracts was observed in association with question schedules a pagnorate, Cataracts. The development of cataracts was observed in association with questiapine treatment in cironic dog studies (see Animal Toxicology in Prescribing Information). Lens changes have also been observed in patients during long-term SEROUEL treatment, but a causal relationship to SEROUEL use has not been established. Nevertheless, the possibility of lenticular changes cannot be excluded at this time. Therefore, examination of the lens by methods adequate to defect cataract formation, such as still tamp exam or other appropriately sensitive methods, is recommended in all intellurated to the control drugs. As with other artisposition streament. Sciences: During clinical artists, secures concurred in 0.6% (182792) of patients treated with SEROUEL compared to 0.2% (1607) on placebo and 0.7% (4627) on active control drugs. As with other artispositions: Evaluate the secure threshold, e.g., Alzheimer's dementia, Conditions that cover the secure threshold, e.g., Alzheimer's dementia, Conditions that was undaraged with a propression during in one chronic therapy, Generally, these changes were of no clinical train which adaptation or progression during more chronic therapy, Generally, these changes were of no clinical train with several conditions that a coverage and was maximian in the first two to clink Hypotyproidiscrution. Ab

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DEVERSE REACTIONS. The information below is derived from a clinical trial database for SERGULE. consisting of ver 2000 patients. This database includes 405 patients exposed to SERGULE. For the treatment of acute bipoter and innormative and adjunct therapy and approximately 2000 patients and in roman subjects exposed to 1 or nor does of SERGULE. For the treatment of acute bipoter main grain (ennotherapy and adjunct therapy) and approximately 2000 patients and in roman subjects exposed to 1 or nor does of SERGULE. For the treatment of schizophrenia. Of this exapproximately 3000 subjects, approximately 2700 (2300 in schizophrenta and 461 in acute bipoter main) were placed to the protripated in multiple dose flectiveness trials, and their apperience corresponded to approximately 914.3 patient-years. The conditions and unation of treatment with SERGULEL variety drepts and include for overlapping categories (per-level and dose-blind phases of studies, impletients and outpetients, fixed-does and dose-litration studies, and short-term of prepare them proposer. Adverse reactions were assessed by collecting diverse events, results of physical cariminaries approximately 4014. Adverse reactions were assessed by collecting diverse events, results of physical cariminaries and proposers and events of the proposers of the proposers of the second proposers of the proposers of t

DRUG ABUSE AND DEPENDENCE: Controlled Substance Class: SEROOUEL is not a controlled substance. Physical and Psychologic dependence. SEROOUEL has not been systematically studied, in animals or humans, for its potier all of abuse, indemance or physical dependence. While the clinical trials do not need any tendency for any drug-seking behavior, these observations were not systematic and it is not possible to predict on the basis of this limited experience the extent to which a OSE-author drug up the misused, diverted, and/or abused force manifeled Consequently, patients should be evaluated carefully for a history of drug abuse, and such patients should be observed closely for signs of misuser or abuse of SEROOUEL, e.g., development of tolerance, increases in dose.

OVERDOSAGE: Human experience: Experience with SEROULE1 (questionire furnarate) in acute overdosage was imited in the clinical ratio database (6 eports) with estimated doses ranging from 1200 mg to 9600 mg are no fatalities. In general, reported signs and symptoms were those resulting from an exaggeration of the drop which was brimated overdose produced signs and symptoms were those resulting from an exaggeration of the drop which are stated overdose of 9800 mg, was associated with hypotalemia and first degree heart block. In post-keing experience, there have been very rere reports of verdores of SEROULE1. Index resulting in death, coma college of the state of

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