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INSIDE THIS ISSUE

Editor's Note: Due to the holidays, *Generic Line* will not be published Dec. 18. The next issue will be published Jan. 1, 2014.

GPhA Asks FDA for More Time to Comment On Proposed Labeling Rule

The FDA's proposed new labeling requirements for generics pose such a challenge to industry that GPhA has asked the FDA for an additional two months to comment on the proposed rule.

GPhA says more time is needed to analyze and provide commentary on the legal and commercial implications of the rule change, which would allow generic drugmakers to change labeling without FDA approval in response to safety concerns.

Current rules allow generic drugmakers to update labeling only as a means of conforming with changes made to the brand-referenced drug's label. This has largely shielded generic makers from injury suits.

(See **Labeling**, *Page 8)*

Second FDA Import Ban Increases Wockhardt's Regulatory Hurdles

The FDA Nov. 27 hit Wockhardt with a second "import alert," banning drug products from its Chikalthana plant in western India — the latest in a spate of regulatory actions taken against the struggling drugmaker.

In May, the agency imposed a ban on products from Wockhardt's Waluj plant, citing issues with the plant's good manufacturing practices. Wockhardt had diverted some production from the Waluj plant to Chikalthana, which is one of the drugmaker's key facilities.

The FDA import alert resulted from violations of GMP and data integrity practices that were observed during a July FDA inspection of the Chikalthana plant, Eric Pahon, an agency spokesman, told *Generic Line.*

(See **Wockhardt**, *Page 6)*

China's Low-Cost Drug Mandate Will Benefit Generic Drugmakers

Chinese authorities are gearing up to keep the cost of certain drugs sold in the country down via publication of a "low-cost" drug list expected to expand access to generics.

The cost-control initiative, the latest plank in China's larger healthcare reform effort, is expected to take hold just as the country is set to become the world's second-largest drug market after the U.S. by 2017, according to a new study by IMS Health. China will represent 34 percent of total growth in global pharma spending over the next five years.

China's National Development and Reform Commission will release the list of drugs that must be sold at low-cost prices, according to Xinhua, the state news organization for China. No timeline was given stating when the list will be released, but sources close to Xinhua say the standard sticker price for low-cost western drugs will be mandated at just under fifty cents a day, or 3 yuan. Chinese patented drugs will be closer to $1, or 5 yuan, according to the news group.

The list, including criteria and cost principles, is expected to be adjusted every two to four years.

The price cap is "essentially price insurance for pharmaceutical companies," allowing a number of low-cost drug manufacturers to either re-enter the market or ramp-up production, Shi Lichen, a general manager of healthcare at PKU Management Consulting Group, told Xinhua. Smaller companies already producing generic drugs in the country will become "hot acquisition targets."

The boon for generic drugmakers could be especially high if China's drug spending continues to grow at its current rapid clip. China's drug spending levels are expected to increase 34 percent and account for 15 percent of total global drug spending by 2017, the IMS Health report states.

The drug costs initiative is not China's first. China earlier this year launched a review of drug pricing and manufacturing costs for nearly 60 domestic and international drug companies, including GlaxoSmithKline, Boehringer Ingelheim, Fresenius Kabi and Sandoz.

Meanwhile, the country continues to crack down on pharma fraud and improve drug quality, an effort that most recently has targeted internet pharmacies operating in the country. — Melissa Winn

Eli Lilly Sues Actavis to Halt Generic Axiron ANDA

Eli Lilly and Acrux on Nov. 12 filed suit against Actavis to prevent the generic drugmaker from commercializing a generic version of the testosterone topical solution Axiron.

The lawsuit, filed in the U.S. District Court for the Southern District of Indiana, will delay any FDA approval of Actavis' ANDA for up to 30 months or until the court resolves the suit.

The agency approved Axiron (testosterone) in November 2010 as a replacement therapy for men with conditions associated with a deficiency or absence of testosterone. Four patents associated with Axiron expire in 2017. Two patents listed in the Orange Book for the drug expire in 2027.

Based on available information, including a submission date listed on the FDA's Paragraph IV patent certifications website, that is consistent with the date of Actavis' ANDA filing, Actavis believes it may be a first applicant to file an ANDA for a generic version of Axiron.

Axiron is sold as a metered-dose pump. One pump actuation delivers 30 mg of testosterone. Each metered-dose pump is supplied with an applicator.

For the 12 months ending Sept. 30 Axiron had total U.S. sales of approximately $257 million, according to IMS Health data. — Melissa Winn

FDA Denies Small Pharma Company's Request for GDUFA Facility Fee Waiver

The Generic Drug User Fee Amendments of 2012 do not allow for a waiver, reduction or postponement of finished dosage form (FDF) facility fees for small and/or foreign businesses, the FDA says in a letter denying a citizen petition submitted by Square Pharmaceuticals.

The agency says it also has no authority to change GDUFA's statutory requirements. Congress would need to pass new legislation amending the FDF facility fee language and the president would have to sign it into law, CDER Director Janet Woodcock writes in reply to Square.

The drugmaker in July asked the FDA to revise GDUFA's annual FDF facility fee requirement to allow for a "one-time FDF facility fee until the approval of the first ANDA" manufactured at the facility. The drugmaker also requested a waiver while the agency considered its petition.

Square Pharmaceuticals argued that GDUFA's annual facility fee requirement is "burdensome and paralyzing to small size companies and/or foreign manufacturers."

Instead, the drugmaker suggested a one-time fee could be charged at the same time the agency issues an approval letter or as a condition of approval for an ANDA. The facility would not be subject to any other fees under GDUFA until the product manufactured at the facility is commercialized, the petition said.

For new drugs approved under the Prescription Drug User Fee Act, the manufacturing facility fees are not charged unless the product is approved and commercialized by the NDA holder, the drugmaker reasoned.

The possibility of financial hardship for small to mid-size generic drug companies was discussed by the pharmaceutical industry and the FDA during GDUFA negotiations and all parties agreed that waivers and exemptions would not be included, the agency's response letter says.

The decision was made "after considering the relatively low amount of expected individual fees" and the benefits to small and mid-size companies that will result from the speedier ANDA review times the fees allow for, Woodcock writes.

Priya Jambhekar of Chrai Associates, who filed the petition on behalf of Square, told *Generic Line* the company hopes some of these

(See **FDF***, Page 4)*

FDA Extends Comment Period on GDUFA Guidance After Website Outage

Drugmakers have 14 additional calendar days to comment on recently revised GDUFA question-and-answer guidance after technical difficulties prevented stakeholders from submitting comments on Regulations.gov.

Comments on the draft guidance were due on Nov. 12, but the government website went down from Nov. 4 through Nov. 13. The new deadline to comment is Dec. 11.

So far, the FDA has only received three comments on the Q&A document.

The guidance updates an August 2012 document on implementation of the GDUFA user fee program, approved in July 2012. It provides new details, including that companies who package an approved ANDA product for the first time are classified as packagers and subject to GDUFA's facility fees (*Generic Line*, Sept. 24).

The GDUFA Q&A wasn't the only guidance affected by the shutdown, and the FDA is reviewing what other deadlines need to be extended.

To read the draft guidance, visit www.fdanews.com/ext/resources/files/11/11-26-13-GDUFAQA.pdf. — Robert King

FDA Investigates Efficacy of Brand, Generic Emergency Contraceptives

The FDA is investigating reports that emergency contraceptives such as Teva's Plan B One-Step lose effectiveness in women over 165 lbs. and don't work at all for women over 175 lbs. Based on its review, labeling changes for the drugs may be forthcoming.

The review was prompted by reports that French drugmaker HRA Pharma, the manufacturer of an identical emergency contraceptive, Norlevo (levonorgestrel), is updating the drug's label to reflect reduced or insufficient efficacy in women over 165 lbs.

The FDA is now reviewing "the available and related scientific information on this issue, including the publication upon which the Norlevo labeling change was based," Erica Jefferson, FDA's director of strategy, told *Generic Line* Nov. 26.

The agency will then determine "what, if any, labeling changes to approved emergency contraceptives are warranted," she said. The original approval of Plan B for use in the U.S. did not include an assessment specific to weight, Jefferson noted.

Norlevo and Plan B One-Step, as well as other one-pill emergency contraceptives, rely on levonorgestrel to prevent unwanted pregnancy when taken within 72 hours of unprotected sex.

A spokesperson for Teva told *Generic Line* the drugmaker has not had an opportunity to review the data submitted in Europe to support the Norlevo label change and therefore "cannot provide comment on the data at this time."

The FDA in June approved Teva's Plan B One-Step for sale without a prescription for all women of child-bearing potential. The approval ended a years-long battle over all-ages access to emergency contraceptives.

HRA Pharma did not return requests for comment by press time. — Melissa Winn

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FDF, *from Page 3*

issues will be addressed when GDUFA comes up for review.

The fiscal 2014 facility fees are:

- U.S. FDF facilities: $220,152;
- Non-U.S. FDF facilities: $235,152;
- U.S. API manufacturing facilities: $34,515; and
- Non-U.S. API facilities: $49,515.

GDUFA requires the FDA to charge facilities located outside the U.S. at least $15,000 more than U.S. facilities, but no more than an additional $30,000 due to foreign-facility inspection costs.

The citizen petition filed on behalf of Square can be read at www.fdanews.com/ext/resources/files/11/11-27-13-SquareCP.pdf.

The FDA's response to Square is available at www.fdanews.com/ext/resources/files/11/11-27-13-Square.pdf. — Melissa Winn

New Paragraph IV Patent Certifications (As of Nov. 18. 2013)

DRUG NAME	DOSAGE FORM	STRENGTH	RLD (Sponsor)	DATE OF SUBMISSION
Clindamycin phosphate and benzoyl peroxide	Gel	1.2 percent/2.5 percent	Acanya	12/20/2012

Generic drugmakers file ANDAs with Paragraph IV certifications on drugs where patent coverage still exists and they intend to market generics before the patent expires if approved.

Teva, Mylan Settle Copaxone Patent Litigation in Europe

Teva and Mylan said Nov. 25 they had reached a confidential agreement to settle patent litigation over Teva's multiple sclerosis drug Copaxone in three European courts.

The companies said certain of their affiliates have agreed to settle and dismiss pending patent litigation involving Copaxone (glatiramer acetate) in the UK, the Netherlands and France.

Teva had filed suit in the three countries, saying Mylan would infringe European Patent Number 0,762,888 with its planned generic version of Copaxone. In countersuit, Mylan attempted to invalidate the patent.

The terms of the settlement are confidential. The European patent will expire in May 2015.

Mylan has been victorious in several patent fights filed in U.S. courts by Teva over Copaxone. The U.S. Court of Appeals for the Federal Circuit in July reversed a district court's ruling, invalidating Teva's American patent number '808 for Copaxone (*Generic Line*, July 31).

The appeals court also declared several patents expiring in May 2014 to be invalid, in addition to the '808 patent expiring in September 2015. The appellate court specifically ruled that the patents were invalid for being indefinite. Four other Copaxone (glatiramer acetate injection) patents, also set to expire in May 2014, were upheld as valid.

The ruling will allow Mylan to launch its generic version of Copaxone "on May 25, 2014, upon expiration of Teva's Orange Book patents, subject to Mylan's final regulatory approval," Mylan CEO Heather Bresch told *Generic Line* at that time.

Also in July, a New York district court granted motions to dismiss filed by Mylan and Sandoz after the companies agreed to abstain from using a method of measuring the active pharmaceutical ingredient for Copaxone that Teva had challenged infringed on four of its patents. — Melissa Winn

OMB Should Return Sequestered User Fees, Lawmakers Urge

The White House Office of Management and Budget's decision to sequester nearly $85 million of FDA user fees is wrong, and should be reversed immediately, lawmakers say.

In impounding the user fees under the 2011 Budget Control Act, OMB misinterpreted sequestration to apply to both congressionally appropriated funds and user fees, say Rep. Kevin Yoder (R-Kan.) and 73 other House members in a letter to OMB Director Sylvia Burwell.

In fact, OMB's decision to sequester the private dollars flies in the face of the fundamental intent of the Budget Control Act, which instituted sequestration to reduce government spending of appropriated funds, the group says.

User fees, paid to the agency as part of an agreement negotiated between drugmakers and the FDA, have no bearing on spending of appropriated funds since they cannot be used to offset any expenses other than drug or device reviews. Sequestration of the user fees only exacerbates the FDA's "severe budgetary constraints," the lawmakers argue, urging the White House office to return the non-tax revenues to the agency.

The sequestration has resulted in $82 million in reduced user fee spending for the FDA, including $36.6 million in prescription drug and biologics user fees under the Prescription Drug User Fee Act and $15.25 million under the Generic Drug User Fee Amendments of 2012 and $2.85 million under the Medical Device User Fee Act programs, according to the lawmakers.

Congressional negotiators are under a Dec. 13 deadline to hammer out a new federal budget proposal for fiscal 2014 and fiscal 2015. As part of those negotiations, Yoder and other lawmakers are trying to shield FDA user fee revenue from any future across-the-board sequestration cuts.

The lawmakers' letter can be read at www.fdanews.com/ext/resources/files/12/12-02-2013-Yoder-OMB.pdf. — Melissa Winn

Wockhardt, *from Page 1*

The FDA's import ban on both plants will remain in place until the company corrects the issues.

"Assessing and re-establishing confidence in a manufacturer's compliance with GMP, including the likelihood of its continued compliance, is a complex, often lengthy, process," Pahon said.

He added that releasing a plant from import alert usually requires a reinspection of the facility and "until the FDA determines that the facilities have established reliable, continuous compliance with GMP, the drug products are deemed by law to be adulterated, and we will not permit them to enter the U.S. market."

With both import alerts in place, the generic drugmaker's bottom line is expected to take a significant blow. The U.S. is Wockhardt's largest market and accounted for 43 percent of its revenue in the quarter ended in September, according to SEC filings.

The FDA's import ban excludes five drugs: the cholinergic bethanechol chloride, the antibiotic ceftriaxone, blood pressure drug enalapril maleate, antiseizure medication divalproex sodium and antidepressant venlafaxine hydrochloride.

Wockhardt had not returned requests for comment at press time.

Wockhardt's GMP issues have also prompted regulatory action by British regulators. Last month, the UK's Medicines and Healthcare products Regulatory Agency withdrew the good manufacturing practice certificate for the company's Chikalthana plant, citing manufacturing issues. The MHRA has allowed the plant to continue operations under a "restricted certificate," supplying only drugs deemed "critical to public health."

The UK earlier this year also banned the import of products from the generic drugmaker's plant in Waluj and later recalled 16 different products manufactured at that plant. The precautionary recall, also due to GMP violations, was one of the largest in "recent times," a spokesperson for the MHRA told *Generic Line* at the time (*Generic Line*, Oct. 23). — Melissa Winn

BRIEFS

12-Year Biologic Exclusivity Under Discussion

In troubling news for biosimilar manufacturers, the U.S., as part of recent Trans-Pacific Partnership (TPP) trade talks, is now considering maintaining the highly-debated 12-year exclusivity period for biologic drugs.

The stay represents a departure from recent White House budget proposals, which sought to reduce the exclusivity period to seven years. The earlier introduction of biosimilars to market would save federal healthcare programs $3 billion over 10 years, some U.S. officials have argued.

Yet, following a full day of discussions Nov. 29, the Office of the U.S. Trade Representative (USTR) said biologic drugs need data protection to offer incentive to companies willing to invest the "enormous" amounts of time and money to develop them.

"Before entrepreneurs (in the United States and across the world) are willing to make the investment in new therapies, they want to know that they will have rights to their own research for a certain period of time in order to see a return on their investments," the USTR added.

Industry groups have argued the issue on both sides, with some agreeing that a 12-year exclusivity period would force Americans to unnecessarily pay higher prices for these drugs for an extended period of time.

Members of the pharmaceutical industry convinced dozens of members of Congress to write the White House shortly after the TPP talks got under way to urge that 12 years of exclusivity be obtained (*Generic Line*, Sept. 27, 2011).

Sandoz to Sell AG of Adderall XR

Shire said Dec. 2 it has agreed to supply an authorized generic version of Adderall XR, its attention deficit hyperactivity drug, to Sandoz.

Under the agreement, Sandoz, the generic arm of Novartis, will exclusively sell the authorized generic version of Adderall XR (mixed amphetamine salts) supplied by Shire from July 1, 2016 in the U.S., Shire said, adding it would receive a royalty on sales.

The drug generated sales of $81.4 million for Shire in the third quarter of this year.

Jubilant Gets Okay for Generic Seroquel

Jubilant has received approval from the FDA to market a generic version of AstraZeneca's Seroquel (quetiapine fumarate) used for the treatment of schizophrenia and acute manic episodes associated with bipolar disorder.

The company expects to launch the product in the fourth quarter of 2014.

Baxter Recalls Nitroglycerin

Baxter has issued a recall for a single lot of the nitroglycerin 5 percent dextrose injection, a drug used for pre- and post-operative hypertension, congestive heart failure at the onset of heart attack and chest pain in certain patients.

The recall, which comes two months after Baxter recalled two dual luer lock caps, is due to particulates found in a single vial of the injectable drug. The affected lot was distributed to healthcare centers and distributors in Colombia, the U.S. and Saudi Arabia earlier this year.

No other lots or vials are affected and no adverse events have been reported, according to the drugmaker. Baxter spokeswoman Deborah Spak said the company is working closely with the FDA on managing the recall.

AstraZeneca Wins Patent Row

AstraZeneca Dec. 3 said the U.S. District Court for the Southern District of New York has ordered Apotex to pay it $76 million in damages for selling a generic version of the acid-reflux treatment Prilosec (omeprazole).

The sale of generic omeprazole between 2004 and 2007 infringed two patents on Prilosec, the court ruled.

Labeling, *from Page 1*

The proposed changes "create an additional burden not anticipated in the business and compliance models of generic and biosimilar manufacturers and marketers," GPhA argues.

A 60-day extension to the comment period, which ends Jan. 12, would allow "all interested stakeholders an opportunity to provide commentary based on a robust analysis" of the various implications of the proposal, the letter, signed by GPhA President and CEO Ralph Neas, added.

The proposed rule nullifies a 2011 Supreme Court decision in the case of *Pliva v. Mensing,* in which the court rejected the notion that generic companies have an obligation to request label changes after new adverse events were found, Daniel Kracov, a partner at Arnold & Porter, says.

If the rule is finalized, generic drugmakers will need specific evidence to fend off lawsuits that claim the drugmaker failed to warn about serious side effects, because the courts could find them liable in the same way they have found brand drugmakers liable for years, Kracov told *Generic Line.*

The proposed rule would present a host of business issues, as well, he said, noting that most generic drugmakers don't currently have systems in place to analyze adverse event reports for signals that would prompt a labeling change.

Shortly after the proposed rule was issued last month, GPhA questioned whether the agency has the authority to issue the rule in the wake of the court's decision (*Generic Line*, Nov. 20). The group also said it is concerned that multiple generic drugmakers could file conflicting safety information for the same generic product, leading to "unnecessary confusion and uncertainty for prescribers and patients."

Comments are currently due on the rule by Jan. 12. — Melissa Winn

Drugmakers to Pay Louisiana $88 Million in Fraud Settlement

Twenty-five drugmakers, including generic drugmakers Ranbaxy and Perrigo, have agreed to pay the state of Louisiana more than $88 million to settle Medicaid and Medicare fraud charges lodged against them as part of the state's continuing crusade to recover funds paid out to drug companies improperly.

The state has already collected more than $238 million by pursuing lawsuits against drugmakers.

The latest settlement brings to a close the initial 2010 lawsuit filed by Louisiana's attorney general James Caldwell accusing more than 100 pharmaceutical companies of inflating drug prices in a bid to increase the reimbursements paid to them by Louisiana's Medicaid program. Caldwell vows to continue prosecutions for overpayments.

Caldwell filed another case against 38 drugmakers earlier this year, accusing the companies of deceiving its Medicaid agency into paying for unapproved drugs (*Generic Line*, Oct. 23).

The 25 companies that agreed to settle the 2010 case include Apotex, Eisai, Eli Lilly, Lupin, Novartis, Taro, UCB and others. — Melissa Winn

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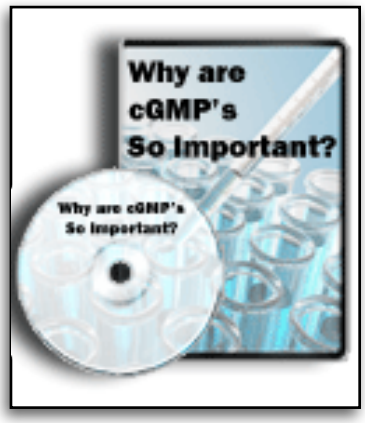

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