

RCS Register

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Pipeline and Hazardous Materials Safety Administration (PHMSA)

Revises Civil and Criminal Penalties

On February 17, 2006 PHMSA revised its regulations to reflect revisions to the civil and criminal penalties. In addition PHMSA revised baseline assessments for violations related to training and security plans. The revised regulations reflect the following statutory changes:

(1) The maximum civil penalty was increased from \$32,500 to \$50,000 for a knowing violation, and up to \$100,000 if the violation results in death, serious illness or severe injury to

any person, or substantial destruction of property.

(2) The minimum civil penalty went from \$275 to \$250, except a minimum civil penalty of \$450 applies to a violation related to training.

(3) Criminal penalties now apply to both reckless and willful violations of Federal hazmat transportation law or the regulations, orders, special permits, and approvals issued.

(4) The maximum criminal penalty of five years imprisonment and a fine of \$250,000 for an individual and \$500,000 for a corporation was retained, except the maximum time of imprisonment has been increased to 10 years in any case in which the violation involves the release of a hazmat which results in death or bodily injury to a person.

Please contact RCS if you have any questions or concerns regarding these changes.

FDA:

Two Executives Convicted in Unapproved Sterilization Device Scheme

CEO and Vice President of Regulatory Affairs for AbTox, a Mundelein, Illinois company, were convicted April 13, 2006, of fraudulently selling un-cleared surgical sterilizing devices that led to eye damage in eighteen patients, causing

them to lose sight in one eye.

Mr. Ross Caputo served as CEO and Mr. Robert Riley served as VP Regulatory Affairs of AbTox when AbTox received permission to market a small gas plasma sterilizer. The small gas plasma

sterilizer was only to be used in sterilizing flat stainless-steel surgical instruments without lumens (tubes) or hinges. Mr. Caputo and Mr. Riley instead marketed a larger, unauthorized version of the sterilizer and promoted its use for a wide array of non stainless-steel instruments.

AbTox showed the hospitals that purchased the larger unauthorized units the clearance

FDA cont. on Page 2

Inside this issue...

A Note from the President

Page 3

Articles

FDA: Unadulterated Conviction
PHMSA: Revised Penalties

Page 1
Page 1

Articles, cont.

EPA: \$6.1 M Settlement
PHMSA: 2005 Summary

Page 2
Page 2

EPA:

6.1 Million Settlement Signed

On April 6, 2006 in San Francisco, the U.S. Environmental Protection Agency (EPA) signed two (2) settlements totaling \$6.1 million. The settlements include two-hundred eighty-three (283) small waste generators that will help pay for the ongoing cleanup of the Casmalia Resources, Superfund Site, near Santa Maria, California.

The announcement is part of an ongoing EPA effort to secure funding for the cleanup of the two-hundred fifty-two (252)-acre landfill, which was designated as a federal Superfund site in September 2001.

The Casmalia Resources site is located about ten (10) miles from Santa Maria, California. The site was an active hazardous waste treatment, storage,

and disposal (TSD) facility from 1973 to 1989. The site accepted approximately 5.6 billion pounds of waste from about 10,000 different generators. The waste was placed into ninety-two (92) waste management facilities that included landfills, ponds, shallow wells, and treatment units.

"In one fell swoop we're releasing hundreds of small parties from liability at the site while securing more funding to address soil and groundwater contamination," said Keith Takata, the EPA's Superfund Division Director for the Pacific Southwest region. "Both of these agreements provide much-needed funding to continue cleanup activities at one of the state's most complex hazardous waste sites."

tion or test packages authorized for transporting hazardous materials.

FDA cont. from Page 1

letter for the smaller, authorized unit. These larger units were then used in an unauthorized manner, because AbTox marketed them that way, to sterilize complex instruments, including cataract instruments that have small tubes, which are used to put solution into the patient's eye. An unauthorized use was to sterilize ophthalmic instruments that had brass joints,

FDA cont.

which reacted to the sterilizing agent creating a toxic residue. AbTox knew of the adverse reaction but did not advise customers or seek proper corrective action.

One hundred sixty eight (168) of the unauthorized units were sold, totaling \$18 million in sales. Hospitals nationwide, including Chicago, IL, Columbia, MO, and St. Louis, MO and the Department of Veterans Affairs hospitals reported to AbTox that their sterilizer was suspected of causing injuries to several patients. A harmful copper acetate residue that remained in the tube of the instrument after sterilization caused blindness by this machine. AbTox also failed to notify the FDA about these reports, which is required.

The conviction of these men is the result of an investigation conducted by the U.S. Food and Drug Administration's Office of Criminal Investigations (OCI). The defendants were convicted of three (3) counts of wire fraud, four (4) counts of mail fraud, seven (7) counts of selling an adulterated (unapproved) or misbranded (mislabeled) human medical device, conspiracy to defraud the FDA and making a false statement for lying to the FDA.

The penalties Mr. Caputo and Mr. Riley face include incarceration, fines and restitution. Two other AbTox employees previously pled guilty in this case.

PHMSA:

2005 Enforcement Summary

For calendar year 2005, The Pipeline And Hazardous Materials Safety Administration (PHMSA) closed a total of 392 hazardous materials civil penalty cases. As a result of those cases PHMSA collected \$1,807,789 in penalties. PHMSA inspection and enforcement staff inspects companies and individuals who offer hazardous materials for transportation or who manufacture, maintain, repair, recondi-

A Note From the President



For every action there is an equal and opposite government program.

~ Bob Wells

Florida Statute 499 read this and weep.

In 1987, the US Congress enacted the *Prescription Drug Marketing Act (PDMA)*, mandating state regulation of the drug distribution market. The reason for this legislation was the fact that pharmaceuticals (including prescription drug samples) that have been mislabeled, misbranded, improperly stored or shipped, exceeded their expiration dates or are counterfeits have been entered into the national (and international) distribution system. To meet this requirement, the Florida legislature passed the state's *Drug Cosmetic Act*, Chapter 499, F.S.1. The Florida Bureau of Statewide Pharmaceutical Services is responsible for enforcing the act, which provides regulatory oversight of drug, device and cosmetic manufacture and distribution in Florida. This act provides for regulatory oversight of the manufacture and distribution of drugs, devices and cosmetics in Florida.

Prescription drug manufacturers, prescription drug wholesalers, retail pharmacy wholesalers, out-of-state prescription drug wholesalers (for persons

located outside Florida), certified designated representative(s), authorized distributors of record and prescription pedigree paper are just a few of the terms with which each business that is required to apply for a permit should become familiar. Regulated businesses must also understand that this statute affects not only companies physically located in Florida, but also out-of-state companies conducting any business in Florida. This article gives a basic understanding of the Florida statute and how it may impact their company's willingness to conduct business within the State of Florida.

The most obvious responsibility of the permitted business is to ensure that prescription drugs are purchased or acquired from an entity that is licensed by the State of Florida to distribute them. In fact, the law requires even companies located outside the state to have a Florida-issued wholesaler's permit. Every supplier must have one of these permits: prescription drug manufacturer, prescription drug wholesaler, retail pharmacy wholesaler or out-of-state prescription drug

wholesaler (for firms in other states). For example, under this Florida statute, an active pharmaceutical ingredient (API) producer is considered a manufacturer of pharmaceutical drugs. Therefore, these firms are required to be licensed in Florida before they can ship their products to any customer located in Florida. Also any business that plans to solicit any out of state company for the purpose importing any drug into the state must also insure that the out of state company has been properly permitted to ship into the state. If due diligence is not performed by the in state company they will be violating Florida Statute 499.005(14) and subject to a fine.

The manufacturer for whom a drug representative distributes prescription drug samples to physicians must be licensed with the Florida Bureau of Statewide Pharmaceutical Services as a complimentary drug distributor. Each license carries a fee and may require an inspection. Additionally, when regulatory professionals send Florida Health and Human Ser-

Florida con't. from Page 3

vices (HHS) a NDC registration, the State of Florida requires the same registration and, a fee is required. An application for a prescription drug wholesaler (including broker only) permit or an out-of-state prescription drug wholesaler permit requires submission of a \$100,000 bond or other equivalent means of security. "Other equivalent means of security" is defined as, "... the security must be in a form that the applicant or permittee cannot revoke, withdraw, cancel, or otherwise reduce the department's interest until the conditions upon which the bond can be refunded or released, as set forth in 499.012 (2), have been satisfied."

Each establishment that is issued a prescription drug wholesaler permit or out-of-state prescription drug wholesaler permit must designate in writing to the State of Florida at least one "natural person" to serve as the wholesaler's certified designated representative (CDR). Before a person can be the CDR, he or she must be certified by the State of Florida (review Chapter 499.012(11) (a),⁴ Florida Statute, and Rule 64F-12.015(9), Florida Administrative Code). One of the many issues that may be encountered is how to be in compliance with both the Florida requirements and 21 *CFR*. How does the CDR inspect returned pharmaceutical products and also meet the requirements of §211.204 for returned drug products? Generally, the

CDR is trained in warehouse operations and drug product shipping but has limited experience with the actual drug product. Therefore, it is necessary to decide whether a duplicate inspection system will be needed to comply with both the act and *CFR*. Additionally, no company may operate under a prescription drug wholesaler permit or an out of state-of-state prescription drug wholesaler permit for more than 10 business days after the designated representative leaves the company. The only exception to this rule is when the wholesale distributor employs another designated representative and notifies the department within 10 business days of the new CDR's identity. Confusing? Yes; basically, if the person designated as an out-of-state firm's CDR leaves, the company must shut down all shipping operations to Florida until a new CDR is in place. Companies located within Florida have to shut down all shipping operations under the same conditions.

Another term that regulatory professionals need to understand is "pedigree papers." Effective 1 July 2006, every person engaged in prescription drug wholesale distribution who is not that drug's manufacturer must, before each wholesale distribution of the drug, provide a pedigree paper, as defined in 499.003 (31). The pedigree paper is intended to provide a chain of

custody from one wholesale distributor to another. Sales to a retail pharmacy, or closed door pharmacy, or directly to the end user, do not require the pedigree paper. A copy of the pedigree paper must be maintained by each recipient and the wholesaler providing it. Once the pedigree paper is signed by a company's authorized representative, the chain of custody is completed and ensures that the drug in question has not been altered. This requirement will not eliminate mislabeled or adulterated drug products; instead, it has the potential to become an additional burden for legitimate pharmaceutical manufacturers and will become a new document to be forged by companies illegally distributing products in Florida.

J. Anthony Daniels

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