Chapter 2 – Center for Devices and Radiological Health

Contents

The Warning Letters presented in this chapter were chosen to provide examples of the types of Warning Letters issued for violations of FDA laws. A complete list of Warning Letters issued is available at: http://www.fda.gov/foi/warning.htm.

Bioresearch Monitoring

Failure to Report Adverse Device Effects Results in Warning Letter

On August 30, 2007, CDRH issued a Warning Letter to Dr. Pamela G. Grady, Director of Peripheral Vascular Clinical Trials, Boston Scientific Cardiovascular, St. Paul, Minnesota. The Warning Letter was based on violations observed during an inspection in May 2007, conducted by an investigator from FDA's Minneapolis District Office. FDA conducted the inspection to determine whether activities and procedures conducted during clinical trials under the direction of Dr. Grady complied with applicable federal laws and regulations.

CDRH reviewed the inspection report prepared by the Minneapolis District Office. The report disclosed serious violations of 21 CFR Part 812, Investigational Device Exemptions, and 21 U.S.C. 360j(g) of the Federal Food, Drug, and Cosmetic Act. The violations noted in the Warning Letter were as follows:

- Failure to immediately conduct an evaluation of any unanticipated adverse device effect;

- Failure to prepare and submit complete, accurate, and timely reports of unanticipated adverse device effects evaluations to FDA, to all reviewing Institutional Review Boards (IRBs) and to participating investigators within 10 working days after first receiving notice of the adverse device effect;

- Failure to provide clinical investigators with the information they need to conduct a clinical investigation properly, and to ensure that any reviewing IRB and FDA are promptly informed of significant new information about an investigation; and

- Failure to submit complete and accurate progress reports at least annually to all reviewing IRBs and to FDA.

The full text of the Warning Letter is available online at: http://www.fda.gov/foi/warning_letters/s6504c.htm.

Clinical Investigator Warned for Failing to Obtain FDA Approval of Clinical Study

On April 3, 2007, CDRH's Office of Compliance issued a Warning Letter to Dr. Thomas Davis, a clinical investigator at St. John Hospital and Medical Center, Detroit, Michigan. The Warning Letter informed Dr. Davis of objectionable conditions observed during an FDA inspection conducted by an investigator from FDA's Detroit District Office. The investigation was conducted at Dr. Davis' clinical site during November and December of 2006.

During the inspection, an FDA investigator documented the following violations:

- Failure to submit an application to FDA for use of a significant risk device in an investigation;
- Failure to obtain FDA's approval prior to beginning an investigation for which an FDA-approved Investigational Device Exemption (IDE) is required;
- Failure to obtain a signed investigator agreement from each participating investigator;
- Failure to ensure proper monitoring of the investigation;
- Failure to maintain records of shipment and disposition of the device to include the name and address of the consignee, type and quantity of device, date of shipment, and batch number or code mark; and
- Failure to ensure that an investigation is conducted according to the investigational plan and applicable regulations.

To view the full text of the Warning Letter, go to:
http://www.fda.gov/foi/warning_letters/b6324d.htm.

Warning Letter Issued Based on Failures of the IRB

On November 7, 2006, CDRH issued a Warning Letter to Mercy Mount Clemens Corporation doing business as St. Joseph's Healthcare Institutional Review Board (IRB), Clinton, Michigan. CDRH issued the Warning Letter based on information obtained by investigators from FDA's Detroit District during an inspection conducted in June and July 2006. FDA's inspection revealed the following violations of FDA regulations:

- Failure of the IRB to review all research activities;
- Failure to conduct continuing review of research;
- Failed to prepare and maintain meeting minutes in sufficient detail;
- Failed to prepare and maintain copies of all research proposals; and
- Failure to review proposed research at convened meetings at which a majority of IRB members are present.

To view the full text of the Warning Letter, go to:
http://www.fda.gov/foi/warning_letters/archive/g6118d.htm.

Warning Letter Issued to Clinical Investigator

Clinical Investigator Fails to Report Severe Adverse Device Effect

On November 8, 2006, CDRH issued a Warning Letter to Bradley Bartholomew, M.D., clinical investigator, located in New Orleans, Louisiana. An investigator from the FDA's New Orleans District Office reviewed Dr. Bartholomew's investigational study in August 2006. During the inspection, the FDA investigator made the following observations as follows:

- Failure to conduct the investigation in accordance with the signed agreement, investigational plan, and conditions of approval imposed by an Institutional Review Board (IRB);

- Failure to maintain accurate, complete, and current records; and

- Failure to prepare and submit a complete and accurate report of an unanticipated adverse device effect within 10 working days after first learning of the effect, to the sponsor and the reviewing IRB.

To view the full text of the Warning Letter, go to:
http://www.fda.gov/foi/warning_letters/archive/g6119d.htm.

Cardiovascular

Consent Decree of Permanent Injunction
Shelhigh, Inc.

On June 22, 2007, the U.S. District Court for the District of New Jersey entered a court order signed by Shelhigh, Inc., Union, New Jersey, in which the firm agreed to stop distributing its implantable medical devices, used in heart surgery and other procedures, until the company brings its production processes in line with FDA standards.

The consent order forbids Shelhigh from distributing all devices until its manufacturing methods, facilities, and controls are in compliance with FDA's CGMP regulation as found in the Quality System (QS) regulation for medical devices. In addition, the firm must come into compliance with FDA's medical device reporting requirements.

Shelhigh manufactures pediatric heart valves and conduits (tube-like devices for blood flow), surgical patches, dural patches (to aid in tissue recovery after neurosurgery), annuloplasty rings (to help repair heart valves) and arterial grafts.

The consent order requires that the company hire independent expert consultants to inspect its facility and certify to FDA that corrections have been made. FDA will continue to monitor these activities through its own inspections.

Shelhigh may resume manufacturing, but not distributing, devices in phases, after FDA has approved its plan for bringing its seized products and manufacturing processes into compliance with FDA law. After Shelhigh has completed corrective actions and been allowed to resume manufacturing, the company must hire an independent auditor to inspect its facility at least once a year. Results of these audit inspections will be reported directly to FDA.

If Shelhigh fails to comply with any provision of the consent order, or violates FDA laws or regulations, FDA may order the company to again cease manufacturing and distributing its devices, to recall the devices, and to take other actions deemed necessary by the Agency, including payment of money for continuing violations.

The consent order was signed by Shlomo Gabbay, Shelhigh's President and Chief Executive Officer and Medical Director, and Lea Gabbay, the company's General Manager.

Seizure of Medical Devices
Shelhigh, Inc.

On April 18, 2007, FDA investigators accompanied U.S. Marshals in a seizure of all implantable medical devices from Shelhigh, Inc., Union, New Jersey. The seizure was initiated after FDA inspections disclosed significant deficiencies in the company's manufacturing practices. The deficiencies may compromise the safety and effectiveness of the products, particularly, their sterility.

The seized products included pediatric heart valves and conduits (tube-like devices for blood flow), surgical patches, dural patches (to aid in tissue recovery after neurosurgery), annuloplasty rings (to help repair heart valves) and arterial grafts. The tissue-based devices are used in many surgical settings, including open heart surgery in adults, children and infants, and to repair soft tissue during neurosurgery and abdominal, pelvic and thoracic surgery. Critically ill patients, pediatric patients and immuno-compromised patients may be at greatest risk from the use of these devices.

The seizure followed an FDA inspection of the Shelhigh manufacturing facility in the Fall of 2006, as well as meetings with the company at which FDA warned Shelhigh that failure to correct its violations could result in an enforcement action. FDA also alerted the company to its manufacturing deficiencies and other

violations in two Warning Letters. Seized Shelhigh products were deemed to be adulterated due to serious deficiencies in the CGMP regulation in accordance with the QS regulation, as described below:

- Manufacturing products in a facility with a poorly constructed and poorly maintained clean room where sterilized devices are further processed;
- Failing to adequately monitor critical manufacturing environments for possible microbial contamination;
- Failing to properly test products for sterility and fever-causing contaminants; and
- Failing to scientifically support product expiration dates.

FDA advised physicians to consider using alternative devices. FDA also advised physicians to monitor patients with a Shelhigh implant for infections and proper device functioning over the expected lifetime of the device.

Warning Letter Issued Following Class I Recall

On April 24, 2007, FDA's New England District Office issued a Warning Letter to Defibtech, LLC, Guilford, Connecticut. The Warning Letter was issued based on the findings of an FDA investigator during an inspection of the firm conducted in March 2007. The inspection was conducted at the Guilford, Connecticut facility following Defibtech's Class I recall of automatic external defibrillators (AEDs).

On March 6, 2007, Defibtech, LLC, initiated a voluntary worldwide recall of the Lifeline AED® and ReviveR AEDTM (semi-automatic external defibrillators). This recall affected all Lifeline and ReviveR AEDs with software versions 2.002 and earlier.

The self-test software for these devices may allow a self-test to clear a previously detected low battery condition. If this situation occurs, the operator may be unaware of the low battery, and the device may be unable to deliver a defibrillation shock, which could result in failure to resuscitate a patient.

The following observations noted by the FDA investigator during the inspection of Defibtech following the recall and cited in the Warning Letter are as follows:

- Failure of the design validation to ensure that the AEDs and battery packs conform to defined user needs and intended uses and to include testing under actual or simulated use conditions; and

- Failure to establish and maintain procedures for implementing corrective and preventive action and document all activities as required by FDA's QS regulation.
- To view the full text of the Warning Letter, go to: http://www.fda.gov/foi/warning_letters/s6343c.htm.

Dental

Civil Money Penalty
TMJ Implants

On September 25, 2007, Administrative Law Judge Daniel J. Davidson ordered each Respondent in this case, TMJ Implants, Inc., Dr. Robert W. Christensen, President, and Maureen K. Mooney, Regulatory Affairs and Quality Assurance Manager, to pay civil money penalties in the amount of $170,000 for failing to file Medical Device Reports (MDR) for 17 device-related adverse events. On July 6, 2007, Judge Davidson issued an Initial Decision finding each Respondent liable for violating the Federal Food, Drug, and Cosmetic Act and the relevant implementing regulation, which requires medical device manufacturers to submit MDRs whenever they receive information that reasonably suggests that one of their marketed devices may have caused or contributed to a serious injury or malfunctioned.

Judge Davidson stayed the assessment of specific penalty amounts pending further consideration of the Respondents' finances. Judge Davidson ordered the Respondents to submit their financial information and stated that failure to fully disclose the financial information would result in the imposition of the full penalty amounts.

Respondents argued that they were unable to pay the penalties and submitted financial documents which purported to show that each Respondent lacked assets. CDRH argued that the Respondents' financial information was incomplete and contained inconsistencies and suggested that the Respondents have substantially more assets than they admit, have alternate sources of income or assets not identified in their financial information, and/or may have transferred assets to other parties or entities to avoid paying the penalties. In imposing the full penalty amounts, Judge Davidson held that the Respondents did not fully disclose their financial information and that their failure to fully disclose gives rise to an adverse inference that a full disclosure would not support their asserted inability to pay. The Respondents had 30 days to appeal the decision to the Departmental Appeals Board (DAB).

Patient Treatment Devices

Consent Decree of Condemnation and Permanent Injunction
Cardinal Health 303 Inc.

On February 8, 2007, Cardinal Health 303 Inc. (Cardinal 303), formerly known as Alaris Medical Systems, Inc., and three of its top executives, signed a consent decree for condemnation and permanent injunction related to their Signature Edition (SE) infusion pumps. The infusion pumps have a design defect referred to as "key bounce" which may cause the pump to recognize a single key stroke as a double key stroke. The "key bounce" problem poses a risk to public health due to a potential over-infusion of medications.

Cardinal 303 agreed to stop manufacturing and distributing all models of the SE infusion pumps until Cardinal 303 corrects manufacturing deficiencies and until the devices are made in compliance with the CGMP regulation as found in FDA's QS regulation for medical devices.

Infusion pumps are electronic devices intended to control delivery of solutions and medications to patients. They are used in situations where medication must be administered intravenously or through other routes, in a continuous or intermittent manner, for a prolonged period of time.

Under the terms of the consent decree, the company agreed to take necessary measures to ensure compliance with the CGMP requirements of the QS regulation by all of its facilities that design, manufacture, process, pack, label, hold, or distribute SE infusion pumps. The decree was signed by Dwight Winstead, Cardinal 303's President and Chief Operating Officer, David L. Schlotterbeck, the company's Chairman and Chief Executive Officer, and William H. Murphy, the company's Senior Vice President of Quality and Regulatory Affairs. The decree also requires the company to retain an independent expert consultant to conduct inspections of its SE infusion pump facilities and certify to FDA that corrections have been made. FDA will continue to monitor these activities through its own inspections.

Under the consent decree, FDA will allow Cardinal 303 to continue to service and repair SE infusion pumps that were already in the hands of customers before entry of the decree. The company is also required to submit to FDA an acceptable detailed corrective action plan to bring the SE infusion pumps currently in use in the United States into compliance with the Federal Food, Drug, and Cosmetic Act (the Act).

The decree was entered in the United States District Court for the Southern District of California on February 8, 2007.

Previously, on August 25, 2006, the U.S. Marshals Service, at the request of FDA, seized several lots of Cardinal 303's SE Gold infusion pumps located at the company's manufacturing facility in San Diego, California. The seizure was intended to ensure that the infusion pumps are not distributed unless the problem was corrected. Cardinal 303 voluntarily suspended production, sales, repair, and installation of SE infusion pumps following the seizure.

On August 15, 2006, the company also voluntarily initiated a field corrective action for all SE infusion pumps, which consisted of sending letters and warning labels to its customers concerning the "key bounce" problem. The FDA classified this action as a Class I recall.

After corrective actions under the decree are completed and Cardinal 303 had been allowed to resume manufacturing and distribution, the firm is required to hire an independent auditor to conduct audit inspections of its SE infusion pump facilities at least once a year for no less than four years. Results of these audit inspections will be reported directly to FDA. If Cardinal 303 fails to comply with any provision of the decree, or violates the Act or FDA regulations, FDA may

order the firm to again cease manufacturing and distributing, recall the products, or take other action.

Warning Letter Issued Following Complaints of Facial Burns

On April 24, 2007, FDA's New England District Office issued a Warning Letter to Rhytec, Inc., Waltham, Massachusetts. FDA conducted an inspection of Rhytec in December 2006 through January 2007. FDA initiated the inspection after receiving complaints of patient facial burns following treatment with the Portrait Plasma Skin resurfacing (PSR3) System. The Warning Letter noted that no MDRs were filed for 12 complaints of serious injury that this device may have caused. In addition, four MDRs were submitted in excess of 30 days.

The firm is a distributor of the Portrait Plasma Skin Resurfacing (PSR3) System. This device uses thermal modification to deliver plasma pulses to the skin. It is marketed for the treatment of rhytides (wrinkles) of the face, skin lesions, actinic keratosis (scaly or crusty bump that forms on the skin surface), viral papillomata, and seborrhoetic keratosis (non-cancerous growths of the outer layer of skin).

The Warning Letter cited the firm for numerous violations of the QS regulation including:

- Failure to establish and maintain adequate procedures for design validation to include risk analysis;
- Failure to establish and maintain procedures for implementing corrective and preventive actions for analyzing sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems;
- Failure to establish and maintain procedures to review, evaluate, and investigate any complaint involving the possible failure of a device to meet any of its specifications;
- Failure to establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities, and failure to document such training; and

- Failure to develop, maintain, and implement written Medical Device Reporting procedures for a standardized review process or procedure for determining when an event meets the criteria for reporting.

To view the full text of the Warning Letter, go to:
http://www.fda.gov/foi/warning_letters/s6341c.htm.

Gastroenterology and Urology

Consent Decree of Permanent Injunction
Custom Ultrasonics, Inc.

On January 25, 2007, a Consent Decree of Permanent Injunction was signed by Judge Timothy J. Savage and Custom Ultrasonics, Inc., (CUI) in the U.S. District Court for the Eastern District of Pennsylvania. In the Consent Decree, CUI agreed to stop manufacturing and distributing its System 83 Plus Washer/Disinfector and the System Plus 83 Mini-flex Washer/Disinfector until it brings the methods and controls used to manufacture the devices into compliance with FDA's CGMP regulation as found in the QS regulation.

In addition, the company agreed to develop and implement adequate written medical device reporting procedures. The company's actions posed a potential public health hazard because endoscopes that are not properly cleaned and disinfected can be a source of transmission of pathogens between patients, causing life threatening infections. FDA is not aware of any adverse events.

FDA advised health care providers using these products to discontinue using them if another option is available and to contact the firm for more information. Other options include using an alternative device or following appropriate protocols to manually wash and disinfect the device. If no alternative is available then health care providers should carefully weigh the risks and benefits of using these products.

In addition to Custom Ultrasonics, Inc., the complaint named as defendant, Frank J. Weber, President and Chief Executive Officer of Custom Ultrasonics, Inc.

In Vitro Diagnostic

Warning Letter Issued to Abbott Laboratories

On March 13, 2007, FDA's Dallas District Office issued a Warning Letter to the Chairman of the Board and Chief Executive Officer of Abbott Laboratories, Inc., Abbott Park, Illinois. The Warning Letter was based on a series of inspections of Abbott's Diagnostics Division in Irving, Texas. The firm manufactures, distributes and installs automated clinical chemistry and immunoassay analyzers. The last inspection was performed in October through November of 2006. Following these inspections Abbott promised corrections. However, these corrections were either ineffective or did not adequately correct systemic quality issues.

FDA's inspections revealed that these devices were adulterated because they were manufactured in violation of FDA's QS regulation and also misbranded because the firm submitted several late MDRs.

The Warning Letter cited eight violations of the QS regulation. Some of these violations included the following:

- Firm management failed to effectively implement adequate and global corrective actions in a timely manner;

- Firm management failed to review all quality sources and take appropriate corrective actions to address various quality issues or document their adequate justification for not taking corrective actions;

- Failure to initiate and implement adequate actions to address potential quality issues with analyzers at the time of the inspection (despite the fact that Abbott had received, in part, 612 worldwide complaints of pressure monitor failures, and factory nonconforming reports documenting 313 pressure monitors);

- Failure of factory testing to adequately detect and reject defective device components, including the pressure monitors and pumps, and nonconforming device functions prior to releasing the analyzers for site installation; and

- Failure of the Inspection Quality Assurance (IQA) unit to follow Abbott's inspection procedures in that the IQA staff used incorrect sampling plans, released components that failed acceptance criteria for production without documenting adequate justification, and did not completely document the types of inspection and secondary checks by peer review.

The inspection also revealed that Abbott's devices were misbranded in that Abbott failed to furnish any material or information respecting the devices as required by the MDR regulation. For example, the firm submitted to FDA several MDRs that exceeded the 30-day timeframe.

The full text of the Warning Letter is available on line at: http://www.fda.gov/foi/warning_letters/b6291d.htm.

Warning Letter Issued to Manufacturer of ELISA Assay Test Kit

On May 31, 2007, FDA's New England District Office issued a Warning Letter to Alerchek, Inc., Portland, Maine, for violations of FDA's medical device regulations. An FDA inspection conducted in May 2007, determined that the firm manufactured the Total Human IgE Quantitative Microwell ELISA Assay test kit. The inspections disclosed that the firm failed to comply with FDA's QS regulation as follows:

- Failure to establish an adequate and effective quality system that has been fully implemented and maintained at all levels of the organization;

- Failure to establish procedures for quality audits;

- Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA) and to document all CAPA activities and their results;

- Failure to evaluate complaints to determine whether the complaint represents an event which is required to be reported to FDA under part 803, MDR;

- Failure to assure that a process whose results can not be fully verified by subsequent inspection and test, has been adequately validated; and

approved according to established procedures;

- Failure to establish and maintain procedures to control all documents;
- Failure to establish and maintain procedures for receiving, in-process, and finished device acceptance activities; and
- Failure to document the equipment identification, calibration dates, the individual performing each calibration, and the next calibration date.

To view the full text of the Warning Letter, go to: http://www.fda.gov/foi/warning_letters/s6398c.htm.

Lasers

Over-Powered Laser Pointers

Several District Offices have been monitoring importation of laser pointers to ensure that they meet the required U.S. Federal Performance Standard, 21 CFR 1040.10. Occasionally samples of laser pointers are obtained upon entry and sent to FDA's Winchester Engineering and Analytical Center (WEAC) laboratory in Winchester, Massachusetts, for evaluation.

WEAC performs laboratory analyses on a wide variety of electronic products such as laser products, television receivers, microwave ovens, ultrasound therapy, cabinet x-ray and medical x-ray.

In one case, FDA's Los Angeles District Import Operations examined a shipment of 1,000 laser pointers that arrived in Phoenix, Arizona, from a Taiwan based manufacturer, Transverse Industries. Samples of laser pointers were sent to WEAC, for routine analysis and compliance testing to confirm that they meet the Federal performance standard for laser products including Class IIIa limits, five milliwatts of power. WEAC's analysis revealed the laser pointers were 13 times more powerful than allowable limit were considered too dangerous for use as pointers or amusement articles.

Non-compliant high powered laser pointers can cause either temporary visual effects or eye injury. WEAC advised CDRH that the laser products were non-compliant and, subsequently, FDA placed Transverse Industries on Import Alert

on November 28, 2007. The Import Alert will automatically refuse entry of all laser products produced by Transverse Industries.

Physical Medicine

Warning Letter Issued to Manufacturer of Wheelchairs and Walkers

On May 31, 2007, FDA's Florida District Office issued a Warning Letter to the Vice President of Healthline Medical Products, Inc., located in Winter Garden, Florida. During an inspection of this firm in February 2007, FDA determined that Healthline Medical Products manufactures several types of medical devices including transport shower gurneys (adult and pediatric), manual wheelchairs, shower/commode chairs, and walkers.

This inspection revealed that these devices were manufactured in violation of the CGMP requirements of the QS regulation. These violations included the following:

- Failure to ensure that an adequate and effective quality system with oversight by management with executive responsibility had been fully implemented and maintained at all levels of the organization;
- Failure to maintain device history records and failure to develop written procedures that ensure that device history records for each batch, lot or unit were maintained to demonstrate that the device was manufactured in accordance with the device master record (DMR) and the QS regulation;
- Failure to maintain DMRs that included or referred to the location of device specifications;
- Failure to formally designate a unit for complaint evaluation to maintain records of investigations;
- Failure to establish and conduct quality audits to verify that a quality system is effective and in compliance with an established quality system; and

- Failure or refusal to furnish material or information respecting the device that is required by the MDR regulation, as follows:

    - Failure to submit an MDR within 30 days of receiving or otherwise becoming aware of information that reasonably suggested that a marketed device may have caused or contributed to a serious injury; and

    - Failure to develop written MDR procedures.

To view the full text of the Warning Letter go to:
http://www.fda.gov/foi/warning_letters/s6392c.htm.

Warning Letter Issued for Devices for Lower Back Pain

On March 2, 2007, FDA's Atlanta District Office issued a Warning Letter to North American Medical Corporation, Marietta, Georgia. During an inspection of this firm in September and October 2006, FDA's investigator determined that the firm manufactures the Accu-Spina and the Da Vinci X10, which are powered traction devices used to relieve lower back pain. FDA's investigator documented nine violations of current good manufacturing practice of the QS regulation. Some of these violations are as follows:

- Failure to document corrective and preventive action activities;

- Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints;

- Failure to document the justification for use of the nonconforming product and the signature of the individual(s) authorizing the use; and

- Failure to perform testing on the design using production units under actual or simulated use conditions.

FDA's inspection also revealed that the firm failed or refused to furnish material or information respecting the device that is required under Section 519 of the Federal Food, Drug, and Cosmetic Act, and the MDR regulation. Significant

deviations documented during the inspection included, but were not limited to, the following:

- Failure of the firm to conduct an investigation of each event and evaluate the cause of the event. For example, a complaint was received which indicated that patients were reporting that the Vibra heat component on an Accu-Spina device was too hot and it burned. The complaint form did not identify the type of burn that the patient experienced or any additional information concerning the incident.

To view the full text of the Warning Letter, go to: http://www.fda.gov/foi/warning_letters/archive/s6485c.htm.

Mammography

Court of Appeals Denies Petition for Review by Korangy Radiology Associates in Civil Money Penalty Case

On August 17, 2007, the United States Fourth Circuit Court of Appeals denied the petition for review filed by Dr. Amile Korangy and Korangy Radiology Associates (KRA), seeking review of an FDA order, which was upheld by the DHHS Departmental Appeals Board, imposing $1.158 million in civil money penalties against Dr. Korangy and KRA for their failure to have the required mammography certification and for performing 192 mammograms while uncertified. Korangy argued that the Mammography Quality Standards Act's (MQSA) provision authorizing penalties did not authorize penalties against KRA. The Court held that, that while the statute did not authorize penalties against "facilities," Korangy was foreclosed as a matter of fact and of procedure from making such argument.

First, Korangy admitted in the proceedings that KRA owned the mammography center and second, he failed to argue that penalties could not be imposed upon KRA because it was the facility and not the owner or operator. Korangy also argued that an FDA guidance manual required FDA to give a facility specific notice, after a certification lapse, that performing mammograms could result in the imposition of civil money penalties. The Court concluded that Korangy admitted receiving notice from the American College of Radiology that his equipment failed the accreditation exam, that he should stop performing

mammograms, and that continued mammograms "may result in official sanction and fines from FDA."

Finally, the Court rejected Korangy's argument that the civil money penalties imposed against him and KRA were excessive in violation of the Eighth Amendment. The Court noted that the civil money penalty of $3,000 per violation was far less than the $10,000 per violation authorized by Congress and that Korangy lost his certification because his equipment failed to produce an image of acceptable quality. Explaining that breast cancer is most curable at its early stages and mammography equipment that fails to produce acceptable images could result in the failure to detect early-stage cancer, the Court concluded that these "grave violations of the MQSA" warranted a substantial penalty.

Mobile Mammography Facility Receives Warning Letter

On August 17, 2007, FDA's New Jersey District Office issued a Warning Letter to American Mobile Medical Surgical Group, Inc., (American Medical), Bordentown, New Jersey. The Warning Letter stated that on June 11, 2007, a representative of FDA inspected American Medical. The inspection disclosed that this mobile facility performed mammography without a valid certificate on 16 occasions from January 10, 2006 through April 5, 2006, and on at least four distinct occasions from October 10, 2006 through November 14, 2006.

Additional violations of the MQSA included the following:

- Phantom quality control records were missing for all days of operation during the period of May 20, 2006, through July 10, 2006 for X-ray unit 1 in the mobile facility;

- Processor quality control records were missing for all days of operation during the period of May 20, 2006, through July 10, 2006, for processor 1 in the mobile facility; and

- The system to communicate results was not adequate for the facility because:

    - There was no system in place to provide timely medical reports;
    - There was no system in place to provide timely lay summaries;

- There was no system in place to communicate serious or highly suggestive cases as soon as possible.

The full text of the Warning Letter is available on line at: http://www.fda.gov/foi/warning_letters/s6542c.htm.

A complete list of Warning Letters issued to Mammography facilities is available on line at: http://www.accessdata.fda.gov/scripts/wlcfm/subject.cfm?FL=M.

Ophthalmic

Class 1 Recall: Alcon Refractive Horizons, Inc.
LADAR6000™ Excimer Laser System

Laser System Found to Cause Corneal Abnormalities and Decreased Visual Acuity

On February 21, 2007, Alcon Refractive Horizons, Inc., initiated a recall of LADAR6000™ Excimer Laser System for CustomCornea® algorithm for myopia with astigmatism (M3), and myopia without astigmatism (A7). The firm initiated the recall because the use of Alcon Refractive Horizon, Inc.'s CustomCornea® algorithm for myopia with astigmatism (M3) and myopia without astigmatism (A7) with the LADAR6000™ Excimer Laser caused corneal abnormalities ("central islands"). It also resulted in decreased visual sharpness (visual acuity). These "central islands" may not be correctable with lasers. Additionally, the decrease in visual acuity may not be correctable with glasses or contact lenses.

Alcon first notified doctors on February 21, 2007, of the problem via letter and recall notice, directing doctors to stop using the CustomCornea® algorithm for myopia with astigmatism (M3) and myopia without astigmatism (A7).

On May 11, 2007, Alcon updated doctors in a letter stating that Alcon will deactivate their device's ability to perform CustomCornea® Myopia and CustomCornea® Myopia with astigmatism procedures. Alcon has completed deactivation of these two algorithms in all LADAR6000™ lasers in service in the United States.

Class I Recall of Contact Lens Solution

On May 26, 2007, FDA issued an advisory alerting health care professionals and their patients who wear soft contact lenses about a voluntary recall of Complete MoisturePlus Multi Purpose Solution manufactured by Advanced Medical Optics. The company took this action as a precaution because of reports of a rare, but serious, eye infection, *Acanthamoeba* keratitis, caused by a parasite. The link between the solution and the infection was identified as a result of an investigation by the Centers for Disease Control and Prevention (CDC).

FDA advised consumers who wear soft contact lenses that they should stop using the solution, discard all partially-used or unopened bottles and replace their lenses and storage container.

Acanthamoeba keratitis may lead to vision loss with some patients requiring a corneal transplant. The infection primarily affects otherwise healthy people who wear contact lenses.

FDA advised that consumers should ask their doctor about choosing an appropriate alternative cleaning/disinfecting product and seek immediate treatment if they have symptoms of eye infection as early diagnosis is important for effective treatment. The symptoms of *Acanthamoeba* keratitis can be very similar to those of other more common eye infections and may include eye pain or redness, blurred vision, light sensitivity, sensation of something in the eye or excessive tearing but *Acanthamoeba* is more difficult to treat.

It is estimated that *Acanthamoeba* keratitis infections occur in approximately 2 out of every 1 million contact lens users in the United States each year. However, in a multi-state investigation to evaluate a recent increase in *Acanthamoeba* keratitis (AK) cases, CDC determined that the risk of developing AK was at least seven times greater for those consumers who used Complete MoisturePlus solution versus those who did not.

Additional information regarding the CDC results is available at the CDC website http://www.cdc.gov/mmwr/preview/mmwrhtml/mm56d526a1.htm.

Warning Letter Issued to Manufacturer of Forceps

On April 25, 2007, the FDA's Cincinnati District Office issued a Warning Letter to Plastics Management Corporation, Sun Valley, California. During an inspection of the firm's medical device manufacturing facility, Kentucky Packing Service, LP, doing business as Olsen Medical, located in Louisville, Kentucky, an FDA investigator determined that the firm, at this location, is the manufacturer of sterile and non-sterile electrosurgical devices, such as bipolar and monopolar forceps, pens/pencils, and electrodes. FDA conducted an inspection of the firm from February 7 – 28, 2007. The following is a list of some, but not all, of the deviations from the QS regulation:

- Failure to fully validate the change in the sterilization process;
- Failure to assure that devices meet all final acceptance criteria prior to distribution;
- Failure to review all associated data and documentation prior to distributing finished devices; and
- Failure to base the finished device sampling plan on a valid statistical rationale.

To view the full text of the Warning Letter, go to:
http://www.fda.gov/foi/warning_letters/s6344c.htm.

Orthopedic

Warning Letter Issued to Manufacturer of Pedicle Screws

On June 25, 2007, FDA's New England District Office issued a Warning Letter to the President and Chief Executive Officer of Innovative Spinal Technologies, Inc., (ISP) Mansfield, Massachusetts. An FDA inspection of ISP in April and May 2007, disclosed that the firm manufactures IST Pedicle Screw Systems and Paramount VBR Screw Systems, which are devices used in the diagnosis and/or treatment of disease.

FDA's inspection revealed that these devices were manufactured in violation of the QS regulation. These violations included the following:

- Failure to identify the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;
- Failure to establish and maintain procedures to control product that does not conform to specified requirements;
- Failure to document the review and approval process when changes or process deviations occurred within the validation of a process;
- Failure to establish and maintain procedures to ensure that all purchased or otherwise received product conforms to specified requirements;
- Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review and approval of design changes before their implementation; and
- Failure to establish and maintain procedures for identifying, with a control number, each unit of finished device that is intended for surgical implant into the body.

To view the full text of the Warning Letter, go to: http://www.fda.gov/foi/warning_letters/s6411c.htm.

Surgical

Warning Letter Issued to Manufacturer of Surgical Tables

On November 29, 2006, FDA's Detroit District Office issued a Warning Letter to the President and Chief Executive Officer of Skytron, Division of the KMW Group, Inc., Grand Rapids, Michigan. The firm manufactures Skytron General Purpose Surgical Tables.

During an inspection of the firm's facility in Grand Rapids, Michigan, in July 2006, an FDA investigator determined that there were serious deviations from the requirements of the QS regulation. These violations included, but were not limited to, the following:

- Failure to inspect, test, or otherwise verify that incoming product conformed to specified requirements;

- Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit;

- Failure to establish and maintain adequate procedures for receiving, reviewing, and evaluating complaints to ensure that these complaints were evaluated to determine whether they represented an event which was required to be reported to FDA; and,

- Failure to review and evaluate all complaints to determine whether an investigation was necessary, or, when no investigation was made, to maintain a record that included the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

The Warning Letter also noted that failure of the firm to comply with the MDR regulation caused the device to be misbranded for the following reasons:

- Failure to develop, maintain, and implement written MDR procedures that provided for timely and effective identification, communication, and evaluation of events that may be subject to the MDR regulation; and

- Failure to submit a written report to the FDA of any correction or removal of a device to reduce the risk to health posed by the device.

To view the full text of the Warning Letter, go to:
http://www.fda.gov/foi/warning_letters/archive/g6153d.htm.

X-Ray

Consent Decree of Permanent Injunction
General Electric Company, doing business as GE Healthcare and GE OEC Medical Systems, Inc., corporations, and
Joseph M. Hogan, and Peter McCabe, individuals

On January 17, 2007, GE OEC Medical Systems, Inc., its parent company, the General Electric Company doing business as GE Healthcare, and two top

executives signed a consent decree of permanent injunction related to X-ray surgical imaging systems manufactured by GE OEC Medical Systems. The consent decree prohibits the manufacturing and distribution of specified GE OEC Medical Systems X-ray surgical imaging systems at facilities located in Salt Lake City, Utah, and Lawrence, Massachusetts. The prohibition against manufacturing and distribution of these surgical imaging systems will remain in place until the devices and facilities have been shown to be in compliance with FDA's CGMP requirements as set forth in the QS regulation for devices.

The X-ray surgical imaging systems subject to the decree were manufactured and designed at GE OEC Medical Systems' facilities in Salt Lake City, Utah, and Lawrence, Massachusetts, and include the 9900 Elite C-Arm System, 9900 Elite NAV C-Arm System, 9800 C-Arm System, 2800 UroView System, 6800 MiniView System, Insta-Trak 3500 NAV System, and ENTrak 2500 NAV System, as well as their components and accessories. These are radiological image processing and image-intensified fluoroscopic X-ray systems that are used during diagnostic, surgical, and interventional procedures, such as orthopedic, cardiac, critical-care, emergency room procedures, and other imaging applications.

FDA's inspection of the Utah facility, conducted between July 31 and August 29, 2006, revealed CGMP deficiencies, including failure to establish and maintain adequate procedures for validating the device design and failure to establish and maintain adequate procedures for implementing corrective and preventive actions. FDA previously inspected the Utah facility between November and December 2004. Following that inspection, FDA issued a Warning Letter on March 31, 2005, citing violations of the CGMP requirements.

The government brought this enforcement action when FDA's 2006 inspections showed inadequate responses to FDA’s requests for corrections in the 2005 Warning Letter.

Under the terms of the consent decree, signed by Joseph M. Hogan, Senior Vice President, GE Company and President and Chief Executive Officer, GE Healthcare, and Peter McCabe, President and Chief Executive Officer of GE OEC Medical Systems and GE Healthcare Surgery, the companies agreed to take necessary measures to ensure that the X-ray surgical imaging systems manufactured and designed at the Utah and Massachusetts facilities comply with CGMP requirements, as well as FDA regulations for reporting adverse events and malfunctions and device corrections and removals.

The decree also requires that the companies hire an independent expert to conduct inspections of GE OEC Medical Systems' facilities in Utah and Massachusetts, and certify to FDA that corrections have been made. Manufacturing and distribution can resume at the Utah and Massachusetts facilities once FDA is satisfied that those facilities are in compliance with the law. An outside expert also must conduct yearly audit inspections for four years to ensure that the facilities remain in compliance and submit the findings to FDA. FDA may order the companies to stop manufacturing and distributing the X-ray imaging systems if they fail to comply with any provision of the consent decree, the Federal Food, Drug, and Cosmetic Act (the Act) or FDA regulations.

Under the consent decree, the companies are also required to submit to FDA a corrective action plan for bringing the firm's devices (the 9900 Elite C-Arm Systems, the 9900 Elite NAV C-Arm Systems, and the 9800 C-Arm Systems) into compliance with the Act that are currently in use in the United States) by physicians, hospitals, and other facilities.

The consent decree allowed the companies to continue to provide routine service maintenance, replacement parts, and accessories for the GE OEC X-ray surgical imaging systems that are already employed in U.S. hospitals and other health care facilities.

Unapproved Devices

Judge Orders Destruction of Seized Devices

On March 30, 2007, U.S. District Court Judge Richard J. Arcara for the Western District of New York signed an Amended Order granting condemnation and forfeiture of Electronic Muscle Stimulator devices valued in excess of 2.7 million dollars. The devices had been under federal seizure at GRE Fulfillment, Buffalo, New York, and were awaiting destruction under the supervision of the U.S. Marshals Service. The seized products were Dr-Ho's Double Massage and Dr-Ho's Muscle Massage, along with various components and accessories.

The Amended Order also granted the Claimant's (Infobeat) motion to withdraw the Claim and Answer, but specifically required the Claimant to pay all costs associated with the storage, destruction and disposal of the seized articles. The devices were manufactured in China and imported into the U.S. through Canada by Dr-Ho Inc., Markham, Ontario.

Warning Letter Issued for Unapproved Device

On January 8, 2007, CDRH issued a Warning Letter to the president of Hardy Diagnostics, located in Santa Maria, California. FDA learned through a voluntary recall, Z-0078-2007, that this firm was marketing the HardyCHROM 0157 in the United States without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act). This recall was conducted due to performance failure.

The HardyCHROM 0157 is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body.

A review of FDA's records revealed that the firm had not obtained marketing approval or clearance before it began offering this product for sale, which is a violation of the Act. The failure to obtain approval for marketing this product results in the HardyCHROM 0157 being adulterated. The firm did not have an approved application for premarket approval in effect or an approved application for an investigational device exemption. Also, the firm did not notify FDA of it's intent to introduce the device into commercial distribution, which is also violation of the Act.

The full text of the Warning Letter is available on line at:

http:// www.fda.gov/foi/warning_letters/archive/g6196d.htm.

Warning Letter Issued for Night Guard

On January 16, 2007, CDRH issued a Warning Letter to Power Products, Inc.-Splintek, (Power Products) located in Kansas City, Missouri. The Warning Letter stated that FDA had learned that Power Products was marketing the Sleep Right® Adjustable Night Guard in the United States for over-the-counter use to protect teeth from clenching and grinding, and for use by children 12 to 18 years old. However, Power Products was marketing this device without clearance or approval from FDA for use by children 12 to 18 years old. A review of FDA records revealed that Power Products had obtained marketing clearance for the Right® Adjustable Night Guard for prescription use only, and for patients 18

years of age or older. However, the firm had not obtained marketing approval or clearance before Power Products began offering the product for over-the-counter use and for use by children 12 to 18 years old, which is a violation of the law.

The Sleep Right® Adjustable Night Guard is a device because it is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body.

Specifically, Sleep Right® Adjustable Night Guard is adulterated because the firm does not have an approved application for premarket approval (PMA) in effect or an approved application for an investigational device exemption (IDE) for use by children 12 to 18 years old. The device is also misbranded because Power Products did not notify the agency of their intent to introduce the device into commercial distribution for use by children 12 to 18 years old.

The full text of the Warning Letter is available online at:
http://www.fda.gov/foi/warning_letters/archive/g6211d.htm.