

---

## Chapter 2 – Center for Devices and Radiological Health

---

### Contents

Bioresearch Monitoring.....	2-2
Cardiovascular .....	2-6
Dental .....	2-9
In-Vitro Diagnostic Devices .....	2-10
Lasers .....	2-12
General Hospital .....	2-13
Physical Medicine .....	2-16
Ophthalmic Devices .....	2-17
Mammography .....	2-18
Orthopedic.....	2-19
Ear, Nose, and Throat.....	2-20
Radiology Devices .....	2-21
Unapproved Devices .....	2-22
Enforcement Statistics.....	2-25

The Warning Letters presented in this chapter were chosen to provide examples of the types of Warning Letters issued for violations of FDA laws. The hyperlinks provided may change and to locate the archived Warning Letters go to <http://www.fda.gov/foi/warning.htm>.

## Bioresearch Monitoring

The objectives of the Center for Devices and Radiological Health (CDRH) bioresearch monitoring program are twofold: (I) to ensure the quality and integrity of data and information submitted in support of investigational and marketing applications or submissions [IDEs, PMAs, and 510(k)s]; and (II) to ensure that human subjects taking part in investigations are protected from undue hazard or risk.

### Failure to Report Adverse Device Effects Resulted in Warning Letter

Clinical Investigator failed to report severe adverse device

On September 5, 2008, CDRH issued a Warning Letter to Dr. Rodney White, Chief of Vascular Surgery, Harbor-UCLA Medical Center, Torrance, California. The Warning Letter was based on violations observed during an inspection from May 21 to June 13, 2008. The Food and Drug Administration (FDA) conducted the inspection to determine whether activities and procedures, conducted during clinical trials under the direction of Dr. White, complied with applicable federal laws and regulations.

The investigation 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 Act).

The violations noted in the Warning Letter were as follows:

- Failure to conduct the investigation according to the signed agreement, the investigational plan, and applicable FDA regulations;
- Failure to obtain, in a non-emergency situation, prior approval by the sponsor of changes in or deviations from the investigational plan and failure to obtain such approval from the reviewing Institutional Review Board (IRB) and FDA,

where the changes or deviations could have affected the rights, safety, or welfare of human subjects; and

- Failure to prepare and submit complete, accurate, and timely reports of unanticipated adverse device effects.

To view the full text of the Warning Letter, go to:

[http://www.fda.gov/foi/warning\\_letters/s6912c.htm](http://www.fda.gov/foi/warning_letters/s6912c.htm)

### **Clinical Investigator Warned for Failing to Obtain FDA Approval for Clinical Study**

---

On June 20, 2008, CDRH's Office of Compliance (OC) issued a Warning Letter to Dr. Anthony Ignagni, President, Chief Executive Officer (CEO) and clinical investigator at Synapse Biomedical, Inc., Oberlin, Ohio. The Warning Letter informed Dr. Ignagni of objectionable conditions observed during an FDA inspection. The investigation was conducted at Dr. Ignagni's clinical site from February 25 to March 18, 2008.

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

- Failure to obtain FDA approval prior to having subjects participate in a study of an investigational device;
- Failure to ensure adequate monitoring of the investigation;
- Failure to obtain from each participating investigator a signed agreement that includes sufficient accurate financial disclosure information to allow the sponsor to submit a complete and accurate certification or disclosure statement; and
- Failure to ship investigational devices only to qualified investigators participating in the investigation.

To view the full text of the Warning Letter, go to:

[http://www.fda.gov/foi/warning\\_letters/s6835c.htm](http://www.fda.gov/foi/warning_letters/s6835c.htm)

---

**Warning Letter Issued Based on Failures of the IRB**

---

On August 14, 2008, CDRH issued a Warning Letter to Aniceta C. Mendoza, Chief of Nursing, of the Valley Baptist Medical Center IRB, Brownsville, Texas. The Warning Letter was based on violations observed during an inspection in April 2008, conducted by an investigator from FDA's Dallas District Office.

The inspection revealed the following violations of FDA regulations:

- Failure to follow written procedures for conducting initial and continuing review of research, and for reporting findings and actions to the investigator and the institution; and ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subjects;
  - Failure to follow written procedures for ensuring prompt reporting to the FDA of: (1) any unanticipated problems involving risks to human subjects or others; (2) any instance of serious or continuing noncompliance with regulations or the requirements or determinations of the IRB; or (3) any suspension or termination of IRB approval.
  - Failure to conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year;
  - Failure to review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas;
  - Failure to require that information given to subjects as part of informed consent is in accordance with 21 CFR 50.25 and failure to require documentation of informed consent in accordance with 21 CFR 50.27;
  - Failure to prepare and maintain adequate documentation of IRB activities, including copies of all research proposals reviewed, approved sample consent documents, and progress reports submitted by investigators;
  - Failure to prepare and maintain adequate documentation of IRB activities, including minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings, actions taken by the IRB, the vote on these actions including the number of members voting for, against, and abstaining, the
-

basis for requiring changes in or disapproving research, and a written summary of the discussion of controverted issues and their resolution; and

- Failure to prepare and maintain adequate documentation of IRB activities, including a list of IRB members identified by name, earned degrees, representative capacity, indications of experience, and any employment or relationship between each member and the institution.

To view the full text of the Warning Letter, go to:

[http://www.fda.gov/foi/warning\\_letters/s6882c.htm](http://www.fda.gov/foi/warning_letters/s6882c.htm)

### **Warning Letter Issued to Sponsor**

---

On February 19, 2008, CDRH issued a Warning Letter to Robert P. Hickey, President and CEO of SyntheMed, Inc., of Iselin, New Jersey, concerning a parallel, multicenter pediatric clinical trial. An investigation of the sponsor was conducted from October 9 to 26, 2007. The purpose of the inspection was to determine whether the sponsor of the clinical study complied with applicable federal regulations.

The inspection was conducted under a program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval (PMA) applications, and Premarket Notification submissions (510(k)) are scientifically valid and accurate. Another objective of the program was to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations.

The inspection revealed the following serious violations:

- Failure to secure the investigator's compliance with the signed investigator agreement, the investigational plan, applicable FDA regulations, and any other conditions of approval imposed by the reviewing IRB or FDA;
  - Failure to ensure adequate monitoring of the investigation and to include written procedures for monitoring in the investigational plan;
  - Failure to accurately document device shipment records;
  - Failure to prepare and submit progress reports at regular intervals and at least yearly to FDA and reviewing IRBs; and
-

- Failure to obtain adequate signed investigator agreements for each participating investigator.

To view the full text of the Warning Letter, go to:

[http://www.fda.gov/foi/warning\\_letters/s6673c.htm](http://www.fda.gov/foi/warning_letters/s6673c.htm)

## Cardiovascular

### Voluntary Recall of Defibrillator and Consent Decree of Permanent Injunction

---

On October 15, 2007, Daniel Schultz, M.D., Director of CDRH, announced that Medtronic, Inc., decided to voluntarily remove its Sprint Fidelis defibrillation leads from the market in the best interest of patient safety.

Implantable cardioverter defibrillators (ICDs) and Cardiac Resynchronization Therapy-Defibrillators (CRT-Ds) are used to treat abnormal heart rhythms that can cause the heart to stop suddenly. ICDs and CRT-Ds shock the heart back into normal rhythm by sending a pulse of energy through an electronic wire or lead that is connected to the heart. The electronic wires in these devices are prone to fracture which can cause the defibrillator to deliver unnecessary shocks or not operate at all. Based on FDA's initial review of reported adverse events, some deaths and major complications have occurred after the leads have fractured. FDA inspections conducted in October 2006 and January 2008 revealed deficiencies of FDA Current Good Manufacturing Practices (CGMP), 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 action.

Previous FDA inspections in 2000, 2003, and 2005 showed similar violations. FDA issued Warning Letters after the 2000 and 2005 inspections, citing CGMP violations.

Medtronic, Inc., announced that it voluntarily suspended worldwide distribution of the Sprint Fidelis family of defibrillation leads. This included four Sprint Fidelis Models: 6930, 6931, 6948, and 6949. FDA considered Medtronic's action to be a product recall. As a result of Medtronic's action, no additional Sprint Fidelis leads will be sold or manufactured and any remaining product should be pulled

---

from inventory and returned to the company. Patients who are implanted with this lead are encouraged to contact their physicians for further information.

On October 15, 2007, FDA issued a Class I Recall for this device. Defibrillators are life-saving products for patients with a heart rhythm abnormality. FDA knows it can be frightening for a patient to learn that a product they rely on so much might have a serious defect. However, patients can be assured that the likelihood of fracture is very low, and the FDA is committed to ensuring that the risk to patients is minimized. Also, FDA recognizes that some patients and health care professionals might inappropriately interpret the word "recall" to mean that the devices must be surgically removed and returned to the manufacturer. Although the leads should no longer be implanted in patients, FDA does not mean to imply that these leads should be surgically removed.

On April 30, 2008, the device manufacturer Physio-Control, Inc., its parent company Medtronic, Inc., and their two top executives signed a consent decree of permanent injunction related to Automatic External Defibrillators (AEDs) manufactured by Physio-Control, Inc.

The consent decree prohibits the manufacture, distribution, and export of specified AEDs at or from Physio-Control's facility in Redmond, Washington, until the devices and facilities have been shown to be in compliance with the FDA's CGMP requirements, as set forth in the Quality System (QS) regulation for devices.

Under terms of the decree, Physio-Control and Medtronic agreed to take necessary measures to ensure that AEDs manufactured and designed at the Redmond facility comply with CGMP requirements and FDA regulations for reporting device corrections and removals.

The decree also provided that the companies be subject to liquidated damages in the amount of \$15,000 per day if they fail to comply with any of the provisions of the decree, and an additional sum of \$15,000 for each violation of the consent decree, the Act, or FDA regulations.

To view the full text of the Press Release, go to:

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01724.html>

### **Vascular Stent not Approved by FDA**

---

On December 19, 2007, OC of CDRH issued a Warning Letter to Vascular

---

Solutions Abbott Vascular, Inc., in Santa Clara, California. The Warning Letter was based on promotional material for the Absolute® Biliary Self-Expanding Stent System (Absolute biliary stent) which the firm promoted at the Vascular Interventional Advances conference held September 25 to 28, 2007, in Las Vegas, Nevada.

FDA reviewed the promotional panel for the Absolute biliary stent which was displayed at the conference. The promotional panel contained statements promoting the Absolute biliary stent for intravascular use. This intended use requires submission of an application for premarket approval. A review of FDA records revealed that the Absolute biliary stent did not have or submit a request for premarket approval from FDA before being offered for this unapproved and promoted use.

OC informed Abbott Vascular, Inc., to immediately cease the display and dissemination of any promotional materials for the Absolute biliary stent that included any mention of intravascular insertion or implantation as an intended use.

To view the full text of the Warning Letter, go to:  
[http://www.fda.gov/foi/warning\\_letters/s6932c.htm](http://www.fda.gov/foi/warning_letters/s6932c.htm)

### **Class I Recalls for Automatic External Defibrillators**

---

AEDs are used by emergency or medical personnel, or by others who have taken the appropriate training to treat cardiopulmonary arrest (heart attacks). The devices analyze an unconscious patient's heart rhythm and automatically delivers an electrical shock to the heart if needed to restore normal heart rhythm.

On October 24, 2008, Welch Allyn Protocol, Inc., recalled Welch Allyn AED 10™, manufactured between March 29 and August 9, 2007. The recall resulted from problems with the defibrillator which may experience failure or cause an unacceptable delay in analyzing a patient's ECG, resulting in possible failure to deliver the appropriate therapy.

On August 28, 2008, Physio Control, Inc. issued a recall of LifePak CR Plus Automated External Defibrillator because the AED instructed the responder, by voice prompts, to press the shock button. However, the shock button was covered and was not visible. Therefore, a responder was unable to deliver the therapy (shock).

---

Both companies advised owners to stop using the AEDs and that the devices would be fixed or replaced.

### **Blood Pumping System Recalled**

---

On March 17, 2008, Levitronix, Inc., of Waltham, Massachusetts, issued a voluntary device correction letter to its U.S. distributor requesting them to notify customers not to use ValleyLab Force FX-X or SSE2L electro-surgery device with the firm's CentriMag Blood Pumping System.

CentriMag Blood Pumping System is used to provide short-term extracorporeal (outside the body) circulatory support during cardiac and other types of surgeries, such as liver transplants. The device temporarily replaces the function of the heart and lungs in order to maintain the appropriate circulation of blood and oxygen levels in the body during the surgical procedure.

This Class I Recall was issued because using the ValleyLab Force FX-X or SSE2L electro-surgery device with the CentriMag Blood Pumping System may result in stoppage of the pump and may cause serious injury or death.

## **Dental**

### **Inspection Revealed CGMP Violations**

---

On September 26, 2008, FDA's Dallas District Office issued a Warning Letter to Sean Moore, President of Alpine Oral Care, LLC, of Houston, Texas. The firm manufactures and distributes mouth guards that are intended for protection against bruxism, particularly nighttime teeth grinding. During an inspection of the firm on July 24, 28, 30, and August 4, 7, and 13, 2008, the investigator reported serious violations to the CGMP regulations.

These violations included:

- Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met;
- Failure to establish and maintain a device design history file for each type of device to include or reference the records necessary to demonstrate that the

design was developed in accordance with the approved design plan and the design control;

- Failure to establish and maintain procedures to ensure that all purchased or otherwise received products and services conform to specified requirements;
- Failure to establish and maintain procedures for the identification, documentation, evaluation, segregation, and disposition of products that do not fulfill specified requirements; and
- Failure to establish and maintain procedures for acceptance or rejection of incoming product, including documentation of acceptance or rejection.

The firm's manager verbally promised to correct the inspectional violations; however, the FDA required written notification of the specific steps that would be taken to correct the noted violations. This response was considered to be inadequate and a Warning Letter was issued.

To view the full text of the Warning Letter, go to:

[http://www.fda.gov/foi/warning\\_letters/s6938c.htm](http://www.fda.gov/foi/warning_letters/s6938c.htm)

## **In-Vitro Diagnostic Devices**

### **Warning Letter Issued to Manufacturer of Cystic Fibrosis Indicator Sweat Test Systems**

---

An inspection of Polychrome Medical, Brooklyn Center, Minnesota, on August 14 through 20, 2007, resulted in a Warning Letter from the FDA. The inspection revealed the firm's Cystic Fibrosis (CF) Indicator Sweat Test Systems were not in conformity with the CGMP requirements of the QS regulation.

These violations included, but were not limited to:

- Failure to maintain device master records that are prepared and approved in accordance with the QS regulations;
  - Failure to develop, conduct, and monitor production processes to ensure that a device conforms to its specifications;
-

- Failure to establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mix-ups;
- Failure to inspect, test, or otherwise verify incoming product for conformance to specifications;
- Failure to establish, define, document and implement procedures for acceptance or rejection of finished device production runs, lots, or batches;
- Failure to establish and maintain procedures for implementing corrective and preventive actions;
- Failure to document corrective and preventive action activities, including analysis of sources of quality data, investigations of causes of nonconformities, the actions needed to correct or prevent recurrence of nonconforming product and other quality problems, the verification or validation of corrective actions, and implementation of corrective and preventive actions; and
- Failure of management with executive responsibility to ensure that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization.

To view the full text of the Warning Letter, go to:

[http://www.fda.gov/foi/warning\\_letters/s6608c.htm](http://www.fda.gov/foi/warning_letters/s6608c.htm).

### **OIVD Sent Warning Letter to LabCorp**

---

On September 29, 2008, FDA's Office of In-Vitro Diagnostic Device Evaluation and Safety (OIVD) sent a Warning Letter to Laboratory Corporation of America (LabCorp) in Burlington, North Carolina, for observations of serious violations of the regulations involving OvaSure™.

OvaSure™ is a test that was designed, developed, and validated by investigators at Yale University. This device was not within the scope of laboratory developed tests over which the agency has traditionally exercised enforcement discretion. FDA's review of OvaSure™ indicated that it was intended for use in the diagnosis of disease or other conditions and requires a marketing clearance or approval from the FDA before distribution.

---

To view the full text of the Warning Letter, go to:  
[http://www.fda.gov/foi/warning\\_letters/s6947c.htm](http://www.fda.gov/foi/warning_letters/s6947c.htm)

## Lasers

### **CGMP Violations for Laser Firm**

---

The FDA on November 30, 2007, issued a Warning Letter to Dr. Bruce Coren, Chairman and CEO of Avicenna Laser Technology, Inc., West Palm Beach, Florida. During an inspection of the firm between July 12 to 13, 2007, investigators cited the firm for serious violations of the CGMP requirements of the QS regulation.

The violations included, but are not limited to, the following:

- Failure to establish and implement written procedures;
- Failure to establish procedures to control the design process;
- Failure to establish procedures for identifying training needs and to ensure that all personnel are trained to adequately perform their assigned responsibilities;
- Failure to establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants;
- Failure to have the signature of a designated individual(s) prior to releasing finished devices for distribution; and
- Failure to implement procedures to control documents required under the QS regulation.

The FDA noted that the existing device design information had changed. The firm discontinued purchasing the Class II medical laser, model VTR-75 manufactured by one original equipment manufacturer (OEM) manufacturer, and replaced it with model AVI-HP 7.5, manufactured by another OEM, without submitting a new 510(k) notice or filing a supplement to the existing cleared 510(k) notice. Also, FDA had not received annual reports for the therapeutic laser system.

---

To view the full text of the Warning Letter, go to:

[http://www.fda.gov/foi/warning\\_letters/s6607c.htm](http://www.fda.gov/foi/warning_letters/s6607c.htm).

### **Laser Hair Brush Lacked Market Approval**

---

On August 7, 2008, the FDA issued a Warning Letter to Dr. Charles Maricle, President of Sunetics International Corporation (Sunetics) of Las Vegas, Nevada, for distributing the Sunetics Laser Hair Brush and the Sunetics Laser Skin Brush without FDA approval.

On January 22, 2008, Sunetics submitted a premarket notification for the Sunetics Laser Hair Brush. FDA requested Sunetics to stop commercial distribution of the Sunetics Laser Hair Brush until FDA issued an order permitting it to be marketed. The Sunetics Laser Skin Brush makes medical claims to relieve pain and to treat various skin conditions such as acne, skin pigmentations, burns, and wounds and requires premarket approval or clearance before distribution.

To view the full text of the Warning Letter, go to:

[http://www.fda.gov/foi/warning\\_letters/s6889c.htm](http://www.fda.gov/foi/warning_letters/s6889c.htm).

## **General Hospital**

### **Class I Recall Issued for Two Medtronic Devices**

---

Class I recalls for implantable infusion pumps and intrathecal catheters
--

On January 16, 2008, Medtronic Neuromodulation (Medtronic), initiated a recall of SynchroMed EL, SynchroMedII, and IsoMed Implantable Infusion Pumps for updated labeling amid reports of inflammatory mass formations at or near the distal tip of intrathecal catheters which infuse therapeutic drugs to patients, and for the devices to include current patient management and treatment recommendations.

On June 26, 2008, Medtronic issued another recall due to the potential misconnections of the Medtronic sutureless connector catheters from the catheter port on the pump.

Medtronic first notified doctors on January 16, 2008, of the pump problem via a letter describing the problem, patient risks, patient management,

---

recommendations, and next steps. In June 2008, the company sent a notification to healthcare professionals describing the problem with the catheters.

The notification identified the:

- Affected catheters,
- Revision kits' model numbers,
- Associated implantable infusion pumps, and
- Recommendations to healthcare professionals.

Please see the firm's notification about the catheters at:

<http://www.medtronic.com/disclosure/product-advisories.html>

### **Recall of Pre-filled Syringes**

---

On January 25, 2008, the FDA announced a nationwide recall of all lots of heparin and saline pre-filled flush syringes manufactured by AM2 PAT, (AM2 PAT) Inc., of Angier, North Carolina. Two lots have been found to be contaminated with *Serratia marcescens*, a bacterium that can cause serious injury or death.

These syringes were manufactured by AM2 PAT, under the brand names Sierra Pre-filled, Inc. and B. Braun. They were sold in fill sizes of 3mL, 5mL, and 10mL, and syringe sizes of 6mL, and 12mL. The company voluntarily recalled these products on January 18, 2008, after confirming bacterial contamination in some user samples. The recall affects all lots of these products.

The FDA received information that Heparin Lock Flush syringes from Lot 070926H and Normal Saline IV syringes from Lot 070917A had been found to be contaminated with *Serratia marcescens*, and had resulted in patient infections. The U.S. Centers for Disease Control and Prevention (CDC) has confirmed growth of *Serratia marcescens* from unopened heparin syringes. Traditionally, *Serratia marcescens*, a bacterium found in water and soil has been linked to pneumonia, blood infections, urinary tract infections, and wound infections. Some patients exposed to the recalled syringes developed blood infections.

To view the full text of the Press Release, go to:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01785.html>

**Warning Letter for Not Conforming with CGMP**

---

The FDA on October 30, 2007, issued a Warning Letter to Larry Cohen, President of International Technidyne Corporation, Piscataway, New Jersey. The firm was inspected February 7 through March 1, and August 6 through 15, 2007, and determined that the ProTime Microcoagulation System (ProTime) was a device because it was intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease. It was also determined that the ProTime device was adulterated in that it was not in conformity with the CGMP requirements.

The FDA carefully reviewed five responses from the company and found them inadequate in that the responses did not completely address all the issues. Some of the issues included:

- Failure to establish and maintain procedures to control product that does not conform to specified requirements;
  - Failure to describe adequate corrections that will prevent future recurrences of rework being performed incorrectly by the contract manufacturer and prevent nonconforming product from being released by the firm;
  - Failure to document corrective and preventive action (CAPA) activities, including investigations of causes of nonconformities, the actions needed to correct or prevent recurrence of nonconforming product and other quality problems, and implementation of corrective and preventive actions;
  - Failure to address the nonconforming product in distribution;
  - Failure to establish and maintain complaint handling procedures to ensure that all complaint files are evaluated to determine whether the complaint represents an event which is required to be reported to FDA;
  - Failure to evaluate for Medical Device Reporting (MDR) submission the complaint files that were cited by FDA investigators as being incomplete for lack of events surrounding complaint closure and/or investigation;
  - Failure to provide any evidence that the firm would ensure that all purchased or received products and services would conform to specified requirements;
-

- Failure to provide any assessments that the contract manufacturer was currently capable of providing ProTime devices that would conform to specifications; and
- Failure to perform a risk analysis that validated the device's design as required.

To view the full text of the Warning Letter go to:

[http://www.fda.gov/foi/warning\\_letters/archive/s6726c.htm](http://www.fda.gov/foi/warning_letters/archive/s6726c.htm)

## Physical Medicine

### Warning Letter Issued to Manufacturer of Patient Rotation Beds

---

An inspection of ProBed Medical Technologies located in Abbotsford, British Columbia, Canada, on May 22 through 25, 2007, revealed violations in the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of powered patient rotation beds. These powered patient rotation beds were not manufactured in conformity with the CGMP requirements of the QS regulation.

This inspection revealed serious violations of the regulations. These violations included, but were not limited to, the following:

- Failure to establish and maintain adequate complaint handling procedures to ensure complaints are reviewed and investigated;
- Failure to establish and maintain adequate corrective and preventive action procedures that address verification or validation of the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device prior to implementation; and
- Failure to establish and maintain design control procedures that define and document design outputs in terms that allow an adequate evaluation of conformance to design input requirements and to contain or make reference to acceptance criteria.

The firm responded to the FDA on June 25, 2007, and FDA concluded that the response was inadequate. The firm did not provide revised design control

---

procedures and failed to establish and maintain adequate design review procedures. The Warning Letter was issued on October 31, 2007.

To view the full text of the Warning Letter go to:

[http://www.fda.gov/foi/warning\\_letters/archive/s6573c.htm](http://www.fda.gov/foi/warning_letters/archive/s6573c.htm).

## Ophthalmic Devices

### Contact Lens Firm Received Warning Letter

---

On September 4, 2008, FDA's Florida District Office issued a Warning Letter to Robert Smart, President of The Lifestyle GP Company, LLC, in Sarasota, Florida. An inspection of the firm on January 29 through February 1, 2008, revealed serious violations to the CGMP requirements of the QS regulation. The firm manufactures a daily wear contact lens.

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

- Failure to establish adequate management controls to ensure that an effective quality system has been established and maintained;
- Failure to adequately maintain procedures for implementing corrective and preventive action and to document all activities and results under this section;
- Failure to fully validate and approve, according to established procedures, processes whose results cannot be fully verified by subsequent inspection;
- Failure to establish procedures for quality audits and conduct such audits to assure the quality system is in compliance with established quality system requirements and to determine the effectiveness of the quality system; and
- Failure to establish and maintain procedures to control all documents.

The firm responded on July 9, 2008, to the FDA's inspectional observations. FDA reviewed the response, and concluded that the responses to some of the observations appear to be adequate. A follow-up inspection will be required to assure that all of the corrections are adequate.

---

The inspection also revealed that the devices were misbranded because the firm failed or refused to furnish material or information on the device as required by the MDR regulation. The response to this violation, as written in the July 9, 2008, letter was inadequate in that the firm's procedures did not require the reporting of life threatening events, permanent damage to body structure, or events that necessitated medical or surgical intervention.

To view the full text of the Warning Letter, go to:

[http://www.fda.gov/foi/warning\\_letters/s6965c.htm](http://www.fda.gov/foi/warning_letters/s6965c.htm).

## **Mammography**

### **MQSA Inspection Leads to Warning Letter**

---

On July 1, 2008, a representative of the State of Texas, acting on behalf of the FDA performed an inspection at Mesquite Diagnostics of Mesquite, Texas, which revealed a serious problem involving the conduct of mammography. Under the Mammography Quality Standards Act of 1992 ("MQSA") which is codified in Section 263b of Title 42 of the United States Code, a firm must meet specific requirements to practice mammography. These requirements serve to protect the health of women by assuring that a facility performs quality mammography.

The Warning Letter, dated July 15, 2008, requested the firm to address in writing the following findings:

- The facility was performing mammography without a valid certificate. [See 21 CFR 900.11(a)].

The firm was asked to respond to provide the following:

- Documentation of the specific steps the firm has taken, or will take, to correct all of the violations, including projected timeframes for implementing those steps;
  - The specific steps taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps; and
  - Sample records that demonstrate proper record keeping procedures.
-

This Warning Letter pertains only to violations related to the recent inspection of the facility and did not necessarily address other obligations the firm has under the law. General information about all of FDA's requirements for mammography facilities are found by contacting the Mammography Quality Assurance Program, Food and Drug Administration, through the Internet at:

<http://www.fda.gov/cdrh/mammography/index.html>.

The full text of the Warning Letter is available online at:

[http://www.fda.gov/foi/warning\\_letters/s6864c.htm](http://www.fda.gov/foi/warning_letters/s6864c.htm).

## Orthopedic

### Warning Letter Issued after Inspection

---

On November 1, 2007, the FDA issued a Warning Letter to Thomas P. Cseplo, CEO of Troy Innovative Instruments, Inc., Middlefield, Ohio. This firm manufactures various tools and implantable orthopedic and neurological devices, including trocars, lumbar bone screws, rods, nuts, plates, and skull pins.

The firm was inspected September 6 through 27, 2007. The Form FDA 483, Report of Inspectional Observations, issued at the close of the inspection contained nine citations revealing that these devices were adulterated and were not in conformity with the CGMP requirements of the QS regulation.

These violations included, but were not limited to, the following:

- Failure to validate manufacturing processes according to established procedures, where the results cannot be fully verified by subsequent inspections and tests;
  - Failure to include in the device history records complete acceptance records that demonstrate the device is manufactured in accordance with the device master record;
  - Failure to analyze all sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems;
  - Failure to ensure that the corrective and preventive actions are effective;
-

- Failure to evaluate and investigate nonconforming product and to adequately control nonconforming product;
- Failure to adequately inspect or test incoming product to verify conformance to specifications;
- Failure to evaluate potential suppliers and contractors;
- Failure to conduct quality audits to verify that the quality system is effective in fulfilling the firm's quality system objectives; and
- Failure to adequately implement the management review procedures.

The full text of the Warning Letter is available online at:  
[http://www.fda.gov/foi/warning\\_letters/s6574c.htm](http://www.fda.gov/foi/warning_letters/s6574c.htm).

## **Ear, Nose, and Throat**

### **FDA Sought Civil Penalties For Cochlear Implant**

---

FDA announced on March 28, 2008, it is seeking a \$2.2 million penalty against a California hearing device manufacturer for violations of federal law, including manufacturing standards violations. Advanced Bionics failed to notify the FDA of a change in an outside supplier or vendor, which may have exposed recipients of the devices to unnecessary health risks.

The cochlear implants posed a public health risk due to accumulation of excessive moisture, increasing the risk of; device failure, secondary infections, corrective surgery, and for additional hearing loss.

On July 7, 2003, Advanced Bionics received FDA approval to market the HiRes90k Implantable Cochlear Stimulator, a cochlear implant surgically implanted under the skin behind the ear to treat profound hearing loss in adults and children. The cochlear implant is considered a Class III device by the FDA – the most stringent regulatory category for devices.

The complaint alleged that the company failed to comply with the FDA's CGMP requirements for devices. CGMP requires that companies manufacturing medical devices for sale in the United States establish and follow quality systems procedures to assure the safety and quality of their products.

---

Advanced Bionics' alleged CGMP violations included the failure to sufficiently evaluate and select a new vendor as the supplier of a critical device component, and the failure to adequately validate the continued safety and effectiveness of the cochlear implant by testing lots under actual or simulated use when the unapproved vendor's component was used.

The complaint also stated that Advanced Bionics shipped cochlear implants in violation of the law between January 2005 and July 2006. Two cochlear implants shipped and implanted after a March 2006 recall contained the component from the unapproved vendor.

On July 14, 2008, the FDA reached a settlement with Advanced Bionics LLC and its President and CEO Jeffrey Greiner over the alleged violations of federal law. Under the terms of the settlement Advanced Bionics will pay a civil money penalty of \$1.1 million. Greiner will pay \$75,000.

To view the full text of the Press Releases, go to:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01813.html>.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01860.html>.

## **Radiology Devices**

### **GE Healthcare/ General Electric Company Received Warning Letter**

---

On November 16, 2007, the FDA issued a Warning Letter to Joseph Hogan, President and CEO, GE Healthcare, General Electric Company, Waukesha, Wisconsin. The New Orleans District conducted field tests of two certified x-ray systems to determine compliance with portions of the Performance Standard for Diagnostic X-Ray Equipment.

During testing on September 27, 2007, x-ray production was possible when the primary protective barrier was not in position to intercept the x-ray beam. The systems tested were assembled by GE Healthcare. FDA requested that GE Healthcare, the responsible assembler, investigate the deviation from the performance standard and/or the defect.

To view the full text of the Warning Letter, go to:

[http://www.fda.gov/foi/warning\\_letters/s6584c.htm](http://www.fda.gov/foi/warning_letters/s6584c.htm)

---

## **Magnetic Resonance Device Recalled**

---

Nebion, LLC, of Los Angeles, California, had their HLX-8 Magnetic Resonance Device recalled because the device was not approved by FDA, lacked safety and effectiveness data, and was not manufactured under CGMP.

The firm's labeling reported that the device could be used to treat many different medical conditions and diseases, such as:

- Cancer (including breast, bone, lung, and pancreatic),
- Carpel tunnel syndrome,
- Migraines,
- Premenstrual syndrome (PMS),
- Rheumatoid arthritis,
- Ruptured disks,
- Shingles, and
- Sports injuries and sprains.

FDA has no evidence to support these claims. Nebion, LLC, contacted each customer who purchased the device and instructed them to stop using the device and return the device at the company's expense.

## **Unapproved Devices**

### **Sterile Water and Sterile Saline Not Approved for Wound Care**

---

A Warning Letter was issued on November 9, 2007, to Kevin Kile, President and Chief Financial Officer (CFO) of Nurse Assist, Inc., Fort Worth, Texas, after an inspection on August 21 through September 12, 2007. The firm manufactures sterile water and sterile normal saline solution of 0.9% sodium chloride that was cleared for device irrigation and not for injection as stated in the firm's 510(k).

The inspection revealed QS violations and Premarket Notification violations. The firm was advised to consult with the Division of Dental, Infection Control, and General Hospital Devices Branch of the Office of Device Evaluation in CDRH to determine whether or not the firm must submit a premarket notification 510(k) should they wish to market the current sterile water and sterile normal saline for wound care or wound irrigation. Two of the 510(k)s that the firm acquired from Welcon (K003402 and K973734) were cleared for device irrigation only.

---

The firm was requested to address all issues in their response to the Warning Letter.

To view the full text of the Warning Letter, go to:

[http://www.fda.gov/foi/warning\\_letters/s6633c.htm](http://www.fda.gov/foi/warning_letters/s6633c.htm)

### **Unapproved Medical Stockings**

---

On November 21, 2007, the FDA sent a Warning Letter to Robert Spalding, President, Venosan North America, Asheboro, North Carolina, after learning that the firm was marketing the Silverline and the Silverline DB medical stockings in the United States without marketing clearance or approval.

The Silverline and the Silverline DB medical stockings were devices because they were intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or were intended to affect the structure or any function of the body. The Act requires that manufacturers of devices that are not exempt obtain marketing approval or clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that new devices are shown to be both safe and effective or substantially equivalent to other devices already legally marketed in this country.

There are many FDA requirements pertaining to the manufacture and marketing of devices. The information needed to submit to the FDA to obtain approval or clearance for devices is described on the FDA Website at:

<http://www.fda.gov/cdrh/devadvice/3122.html>.

To view the full text of the Warning Letter, go to:

[http://www.fda.gov/foi/warning\\_letters/s6883c.htm](http://www.fda.gov/foi/warning_letters/s6883c.htm)

### **Warning Letter Issued for Unapproved Device Use**

---

The OC, CDRH, sent a Warning Letter on November 28, 2007, to David Marcarian, President, Precision Biometrics, Inc., of San Carlos, California. CDRH learned the firm was marketing the MyoVision 8000 Static Surface EMG System (M8) and the Dynamic Surface EMG System (D4) in the United States for new intended uses that go beyond the marketing clearance of the firm's 510(k) from the FDA.

---

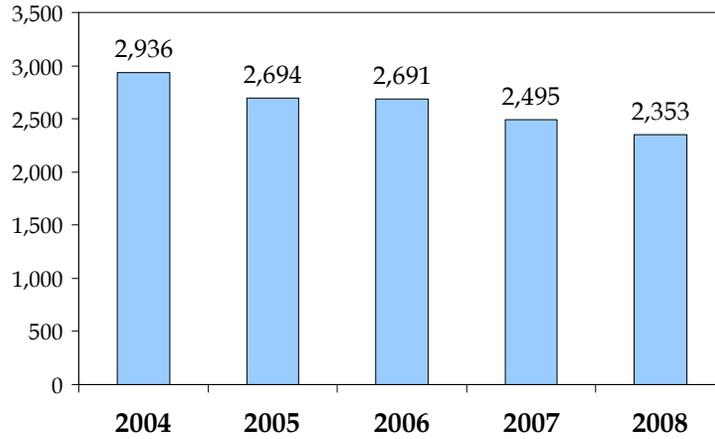
The 510(k) submission did not support diagnostic indications such as evaluating which areas/levels of the nervous system were being adversely affected by Vertebral Subluxations. The FDA requested that Precision Biometrics, Inc. immediately cease marketing the Static Surface EMG System (M8) and the Dynamics EMG System (D4) for the new intended uses that go beyond the marketing clearance from the FDA.

To view the full text of the Warning Letter, go to:

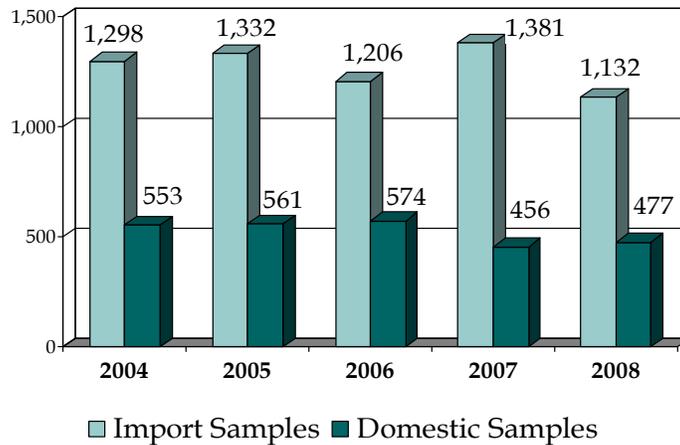
[http://www.fda.gov/foi/warning\\_letters/s6596c.htm](http://www.fda.gov/foi/warning_letters/s6596c.htm)

### Enforcement Statistics

Center for Devices and Radiological Health  
FDA Foreign and Domestic Inspections  
Fiscal Years 2004 - 2008

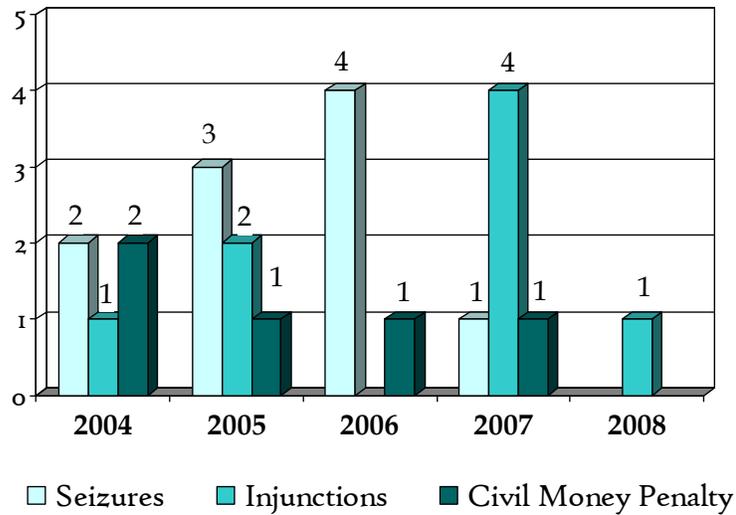


Center for Devices and Radiological Health  
Surveillance: Import and Domestic Samples  
Fiscal Years 2004 - 2008





Center for Devices and Radiological Health  
Enforcement Activity  
Fiscal Years 2004 - 2008



Center for Devices and Radiological Health  
Five-Year Total Product Recall Statistics  
Fiscal Years 2004 - 2008

