MedSun
Medical Product Safety Network

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

March 2019

Volume 19, Issue 3

In This Issue:

About the MedSun Program:

The MedSun Program, which was launched in 2002 by the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), involves the reporting of problems with medical products from a network of approximately 300 hospitals, nursing homes and home health facilities around the United States. MedSun sites work collaboratively with the FDA to assist in detecting, understanding, and sharing information concerning the safety of medical products. MedSun utilizes a secure, on-line system for reporting problems with the use of medical devices. MedSun plays a critical role in FDA's postmarket surveillance efforts.

Those who are interested in having their healthcare facilities join MedSun may contact **medsun@fda.hhs.gov** or 800-859-9821 for additional information.

Newly Approved Devices

Recently Approved Devices (searchable listing):

https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm596872.htm

Premarket Approval Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm595393.htm

510(k)s Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm589381.htm

In Brief

As of March 1, 2019

For the FDA Enforcement Report containing the most recent Class I, II and III recalls, go to
http://www.accessdata.fda.gov/scripts/ires/index.cfm

If you see any problems of the type described in these announcements or other device safety issues, please report them through the MedSun reporting system at https://medsun.fda.gov as soon as possible. If you need password information or want to report by phone, please call us at 1-800-859-9821 or e-mail at medsun@fda.hhs.gov.

Recalls and Safety Alerts

Physio-Control Recalls LIFEPAK15 Monitor/Defibrillator Due to Risk of Device "Lockup" (Freezing)

February 27, 2019

Physio-Control is recalling its LIFEPAK 15 Monitor/Defibrillator because the device may "lockup" (freeze) after a shock is delivered. When this occurs, the device's monitor display goes blank and there is no response from the keypad or the device although the device's LED lights remain on and indicates the device still has power. Once the LIFEPAK 15 freezes, it cannot provide defibrillation therapy until the device is reset by restarting the device or removing and reinserting all connected power sources. The resulting delay in delivering a shock could and has resulted in serious patient injury including death.

ICU Medical Recalls ChemoLock Vial Spike (20mm) Due to Risk of Detached Plastic Particles

February 22, 2019

Recalling of one lot of ChemoLock Vial Spikes, 20mm due to the potential for plastic particles to break off the protective cap. In uncommon circumstances a plastic particle could enter the drug delivery system and be infused into a patient's intravenous line, which could potentially enter the patient and lead to an embolism. To date, ICU Medical has not received any reports of adverse events related to this issue, although the risk of introducing foreign particulates into the patient's body, can cause serious injury or death.

Medtronic, Inc. Recalls Dual Chamber Implantable Pulse Generators (IPGs) Due to Possible Circuit Error

February 15, 2019

Medtronic is recalling its dual chamber IPGs due to the possibility of a software error that can result in a lack of pacing. Patients and physicians cannot predict whether and when this software error might occur. A lack of pacing could result in patients experiencing slow heart beating, low blood pressure, and symptoms such as light headedness, fainting, and even death.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during February 2019. The reports are displayed within clinical specialty areas based on analysis of the information submitted. The reports are presented as submitted by MedSun Representatives and in some instances have been summarized and/or edited for clarity.

A database of all MedSun reports can be found at:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/SearchReportText.cfm


Special Note:

The lollipop icon distinguishes highlighted reports that describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations. FDA defines pediatric patients as those who are 21 years of age or younger (that is, from birth through the twenty-first year of life, up to but not including the twenty-second birthday) at the time of the diagnosis or treatment.

Device	Manufacturer	Problem
Device 1: Allofuse Cortical Cervical Spacers Brand: Allofuse Cortical Cervical Spacers Cat #: 45215006 **Device 2: Allofuse Cortical Cervical Spacers** Brand: Allofuse Cortical Cervical Spacers Cat #: 45215007	AlloSource, Inc. AlloSource, Inc.	After discharge the physician discovered the fracture on a post op x-ray. Physician has used the 4521 series of cervical spacers for years. Over the last year he has now had 3 spacer fractures shown on post op x-ray checks. The 3 surgeries were within the last 12 months. He is not going to continue using them. He has applied bone stimulators to promote fusion and hopes that he does not have to re-operate. The physician stated there was a good chance that one of the patients will have a revision directly related to the spacer failure.

Device	Manufacturer	Problem
Close Antineoplastic Transfer System Brand: Phaseal	Becton Dickinson	The patient was sent home with a twenty-four hour Yondelis chemo infusion. The patient shared that approximately twelve hours into the infusion she got up to go to the bathroom. When she stood up, she noticed that her feet were wet. The patient noticed the chemo dripping out of the bag. Patient went to local Emergency Room, where they cleaned up, managed the spill, and flushed her port. The patient received about 50% of the dose that is given once every three weeks. The patient was unable to complete her therapy, as it is unclear exactly how much drug she got and how much was spilled. This was very disappointing for pt, who had traveled home, which is about one hundred miles from our hospital. The patient reported that the spike broke on the chemo. She took pictures of the Phaseal spike that broke (attached). The break in the Phaseal can be seen by enlarging the top picture (the spike is completely broken off hub). Reassurance provided to the patient. The carrier bag was replaced with an extra large carrier bag for use with the next infusion of chemotherapy. We do not have the exact lot number of the faulty Phaseal spike. Please see pictures below: 

Device	Manufacturer	Problem
		
Device 1: Defibrillator Monitor Brand: Zoll R-series Model#: R-Series **Device 2: Aid, Cardiopulmonary Resuscitation** Brand: Onestep Cpr Aa Model#: 8900-0225-01 Lot #: 4518 Cat #: 8900-0225-01	Zoll Medical Corporation BIO-DETEK INCORPORATED	While performing the daily defibrillator check the RN noted that the defibrillator did not indicate the 30 joule test shock to the multi-function electrode pad. Standard procedure is to connect defibrillator therapy cable to the un-opened Multi-function electrode package to act as a test load for the test shock. When the user initiated the self test the defibrillator passed all checks except when trying to manually deliver test shock. The defibrillator displayed a "Please Replace Pads" message. This same error would occur even with a different multi-function electrode attached. When the clinician inserted the therapy cable into the side defibrillator test port, the defibrillator would pass all self tests including the Test Shock. Unit removed some service and sent to Biomedical for repair. Biomedical confirmed defibrillator's failure to complete user self test with attached multi-function electrode.

Device	Manufacturer	Problem
Dressing, Wound, Occlusive Brand: Allevyn Dressing Lot #: 20830 Other #: 66301307	Smith & Nephew, Inc.	Including this sample patient we have had approximately 9 instances since the last 3 months of wound dressings (sacrum, coccyx, foot, buttock, back, etc.) having caused skin irritation/pain upon removal, silicone staying on sheets of dressing backing when removed, no silicone left of dressing surface, and dressings not sticking (despite use of skin prep to aid in adhesion). For this sample patient, when removing the sacrum dressing it was very uncomfortable to remove; silicone from the dressing stayed adhered to patient's skin. RN tried warm soap & water adhesive remover, scrubbing - nothing would not remove silicone (leaving on patient's skin).
Electrosurgical, Cutting & Coagulation & Accessories Brand: Mega Soft Reusable Patient Return Electrode Model#: M2K07 Cat #: M2K07	Megadyne Medical Proucts, Inc.	They were prepping to operate when someone noticed that the cable wasn't attached to the reusable return pad, but the indicator light on the front of the Megadyne showed green indicating a good contact with the return pad. Investigation showed that the pins were shorted together in the pigtail cable (#M2K07) that goes between the return pad and the longer cable (#M2K01) to the return pad monitor on the front of the Megadyne. I contacted Ethicon and reported the issue. I replaced the cable, tested the unit, and returned it to service.
Enteral Syringe, Specific Brand: Monoject Model#: 8881135015 Lot #: 631958 Cat #: 8881135015 	Cardinal Health, Inc.	A 35 ml enteral feeding syringe was taken from stock to be used to feed a NICU baby. Upon inspection of the syringe, a jagged piece of plastic was seen inside the unused syringe. The 35 ml syringe that was being used had A1 on top of the syringe. The piece of plastic within the syringe appears to be a broken edge of a top of a syringe and has an A8 on top of it. Manufacturer's response per hospital reporter. Covidien stated that this device is now part of Cardinal Health as of July 28, 2018.
Gown, Surgical Brand: Convertors Lot #: 18KBJ027 Cat #: 9575	Cardinal Health 200, LLC.	A non-reinforced surgical gown came from the manufacturer wrapped improperly rendering it non-sterile. This was noticed before it was opened to the surgical field; however, had it been opened it would have contaminated the entire field. The gown was set aside in the wrapping and the information will be circulated though the unit to provide education and prevent contamination of any cases.

Device	Manufacturer	Problem
Gown, Surgical Brand: Convertors Model#: 9575 Lot #: 18KBJ027 Cat #: 9575	Cardinal Health 200, LLC	The dust cover was taken off of a sterile gown to open it onto the operative field and noticed that the blue wrap was not fully covering the gown, therefore making the gown contaminated. The gown with identifying paper work to the manager. This is not the first time this has happened. The gowns are coming from the manufacturer this way.
Image-intensified Fluoroscopic X-ray Brand: O-arm	Medtronic Navigation, Inc.	The O-arm did not work for case. The Medtronic rep was contacted and recommended Biomed in facility as they were not available. In-house Biomed unable to fix. The procedure continued without O-arm. There was no harm to the patient.
Infusion Pump Brand: Alaris Model#: 8100 Other #: 10938662	CAREFUSION 303, INC.	RN had D5 1/2 normal saline one liter bag that was programmed to be infusing at 125cc/hr. The pump appropriately alarmed when IV bag infusion was completed. The RN wanted to re-program the pump to 20ml/hr to allow enough time to get another new bag to switch out without air entering the lines. As the RN was trying to re-program the pump, it would not reprogram after several attempts. RN shut off the pump and rebooted, then the pump allowed her to reprogram. RN took the pump out of service for Biomed review.
IV Pump Infusion Module Brand: Alaris Pump Module Model#: 8100 Other #: 10151657	CAREFUSION 303, INC.	RN reported that pump had been running Levophed to maintain patients blood pressure using max dose permitted. RN return to room less than 5 minutes and found pump off. Blood pressure was not affected when it was discovered. Drip immediately restarted. A concern because could have caused a significant drop and hypoperfusion.
Device 1: IV Pump Module Brand: 0500890000-2019-8005 Model#: 8100 Cat #: 8100ADXEN917 **Device 2: IV Pump Module** Brand: Alaris Model#: 8100	CAREFUSION 303, INC. CAREFUSION 303, INC.	As I was inspecting this device, I noticed that every pump has what appears to be a gap between the membrane and the case. I had removed the membrane and there is a hole there with nothing covering it. The hole is used to hold the membrane in place. The hole leads directly into the electronics of the pump. If this were to get saturated with fluid it could cause corrosion to the electronics of the pump.

Device	Manufacturer	Problem
Device 1: Light Source, Fiberoptic, Routine Brand: Light Cable 3. 5mm Model#: 495ND Lot #: UU04 **Device 2: Light Source, Fiberoptic, Routine** Brand: Coupler	Karl Storz GmbH & Co. KG Unknown	During a hysteroscopy, the Karl Storz light cord detached from the MyoSure hysteroscope and fell onto the drape covering the patient. The light source was removed immediately from the drape when this occurred, but the patient sustained a burn to her abdomen. There is a coupling that is used between the light cable and the hysteroscope. The coupling only has a few threads that screw into the light cord, making it easy for the cord to detach from the light source, which is very hot. The other end that screws into the hysteroscope has many more threads and keeps the scope securely attached.
Plate, Bone Model#: 78-30020 Lot #: 1811021004 Cat #: 78-30020 Other #: Custom mandible plate implant; Sterilizer load# 110118204	STRYKER LEIBINGER GMBH & CO. KG	A custom mandible plate implant was sterilized in preparation for surgery. After the sterilization cycle, the implant was discolored and did not look like a normal implant. The implant is made from anodized titanium and normally has a gold color. After processing, this implant became purple/blue and splotchy looking on the surface. The implant was not used. There was no patient involvement. The surgery was scheduled for a few days later.
Pump, Infusion Brand: Medfusion 4000 Model#: 4000	SMITHS MEDICAL ASD, INC.	Multiple Medfusion 4000 pumps in hospital fleet require a main board replacement but Smith's does not have the part available.Several months ago - 20 boards ordered by hospital. Two weeks later - 50 boards ordered by hospital. Two weeks later - Requested update from Smith's Medical were told they were back ordered and expected stock available in 2 weeks. Next week - Hospital staff member told in person at Smith's Medfusion training that board delay was due to boards failing function checks with the manufacturer. When boards were expected - Hospital checked in since this was the expected date of new stock. Smith's replied still on back order and waiting on release dates from production A month later - Follow up again and was told supplier was estimating a few weeks later for parts availability. A few weeks later - Requested update and Smith's replied sending 10 boards overnight but 60 boards still back ordered. Expected in 2-4weeks. A few days later - Smith's reached out if issues were resolved replied back with our information on ongoing issue. A few days later - Smith's reached out with proposal to swap out pumps that hospital sends in not as loaners but reassign ownership. They noted that expected date of 2 weeks later for new boards was not guaranteed. A few days later - Hospital sent Smith's list of serial numbers that need to be swapped out and is awaiting further instructions. The board shortage has created a pump shortage with 18 pumps out awaiting service for that reason alone and over 30 when all other failures included. This can delay patient care and also create the potential for patient harm. Swapping out units will still be time consuming and as seen from the timeline the communication on when the part is available is not adequate for repairing devices and returning them to use.

Device	Manufacturer	Problem
Device 1: Pump, Infusion Brand: Alaris **Device 2: Set, Administration, Intravascular** Brand: Alaris, Smartsite Model#: 2426-0500 Cat #: 2426-0500	CAREFUSION 303, INC. CAREFUSION 303, INC.	Patient's nurse noticed an unusual "bubble" in the IV tubing from a BD Alaris Pump Infusion Set with back Check Valve - ref # 2426-0500. The bubble was noticed when the nurse unloaded the IV tubing from the Alaris CareFusion infusion pump. The "bubble" is in the portion of the tubing that goes into the peristaltic portion of the infusion pump. No pump alarms sounded. The "bubble" is 2 cm long and 1.5 cm in diameter. As far as the nurse could tell the bubble in the tubing did not interfere with the operation of the pump or the delivery of the medicine. Unfortunately the tubing package was not available to get the lot number. Based on the lot numbers of the extra packages in the patient's nurse-server care it is possible that the unusual tubing was from one of these three lot numbers: (10) 18113112, (10)181113126 or (10)18116462. The IV pump Serial Number was not recorded. It remains in use within the facility.
Safety I. V. Catheter Kit Brand: Medikit Supercath 5 Model#: SP125-24-19Y Lot #: 18D12KA Cat #: SP125-24-19Y 	ICU Medical Inc.	Infant needed a venous blood draw. Patient has a history of being a difficult stick so bedside RN decided to use IV catheter to obtain venous blood. On second attempt, a Medikit Supercath 5, 24 g, 3/4" IV catheter was used. Flashback was obtained, RN retracted needle and placed safely covered sharp on bed as we attempted to aspirate blood. Once we realized the vein was not bleeding back, we removed the hub from the vein. We went to pick up all the trash (chloraprep, IV packaging, and sharp) in the bed and realized the plastic housing that was supposed to be holding the retracted sharp from the IV catheter completely fell apart. There were two plastic pieces and the spring; the needle was nowhere to be found. I as well as bedside RN carefully examined patient and once finding needle was nowhere on her, gave her to MOB (Mother Of Baby) to hold while we carefully removed and examined every piece of linen from bed. We then looked in sharps container to see if the missing needle was thrown away with first venous blood draw attempt sharp; it was not in there. We then flashed a flash light and searched the floor and crib carefully and were unable to locate the missing needle. We then started to carefully remove every item under the crib (diapers, wash clothes, dry wipes, etc.) and eventually found the needle loose and completely exposed under the crib near patient's diapers and blue chux underpad. All parts to IV catheter including packaging (minus IV hub where flashback blood was present and discarded in sharps container before realizing the plastic housing had fallen apart) were collected, placed in biohazard bag, and given the managers. Loose needle was secured into one of the plastic housing pieces to prevent needle stick injury.
Set, Administration, Intravascular Brand: Maxplus Model#: MP5310-C Lot #: (10) 18106550 Cat #: MP5310-C	CAREFUSION 303, INC.	The IV loop "MaxPlus pressure rated extension set with clear needleless connector" has a small blue piece that recoils to close the IV connection and keep pressure in the tubing. When disconnecting LureLock syringes of any kind the blue piece will inconsistently stay depressed, allowing for fluids/blood to leak back out of the tube. A patient could lose a significant amount of blood if this were to go unnoticed.

Device	Manufacturer	Problem
Stylet, Tracheal Tube Brand: Gliderite Single-use Stylet Small 3. 0-4. 0mm Model#: 0803-0118 Lot #: GS43228 Cat #: 0803-0118 Other #: Small 3.0-4.0mm 	Verathon Medical	During intubation of patient at outside hospital by the transport team, the stylet broke off within the endotracheal tube. The patient was ventilating and oxygenating well upon arrival at the hospital. The broken stylet did not appear on the x-ray and was not discovered until the endotracheal tube was removed.
System, Imaging, Pulsed Doppler, Ultrasonic Brand: Siemens Acuson S2000 Model#: Acuson S2000	Siemens Medical Solutions, Inc.	The end user stated, "Ultrasound machine on standby, but while doing portable went through "syngo", a complete shut down. 12 minute delayed service, tech at patient's bedside while machine does complete shut down twice in a row." My understanding is that while they were using the machine it did a complete shut down. We had Siemens the manufacturer come out and they stated that the stand by battery needed to be replaced. This battery had been replaced only 2 months ago.
System, Surgical, Computer Controlled Instrument Brand: Endowrist Stapler 45 Model#: 470298-11 Lot #: T10180109 Other #: Intuitive Assembly stapler 45, IS4000	Intuitive Surgical, Inc.	During Resection of Colon Robotic the 45 mm Intuitive Robotic Stapler began to malfunction. Stapler was moving uncontrollably in all directions. OR tech able to grab the arm and make it stop. Arm with trocar and stapler in place removed. Another stapler applied and procedure finished with no injury or adverse outcome. Stapler sent out to Intuitive for evaluation.
Blood Gas Analyzer Brand: Gem 4000	Instrumentation Laboratories	During the monthly review of the September IQM data for the GEM 4000 blood gas analysis instrument, it was discovered that the report was not generated by one of the instruments. During the subsequent monthly review another instrument failed to generate the report. The vendor was contacted and a service ticket was opened. The is Instrumentation Laboratories.

Device	Manufacturer	Problem
Device 1: Unit, Neonatal Phototherapy Brand: Neoblue Lot #: N102518-04 Cat #: 006245 **Device 2: Unit, Neonatal Phototherapy** Brand: Neoblue- Lot #: N092418-01 Cat #: 006245 	NATUS MEDICAL INCORPORATED NATUS MEDICAL INCORPORATED	Received replacement Natus bili blanket/light source from Natus. During inspection by Biomed Engineering, noticed the connector had cracks. Natus was informed of the findings and replacements were sent out. Upon inspection of new batch, identified crack in one of the products. Natus was contacted again and stated that they would stop all shipments until Quality Control addressed the issues.
Stent, Superficial Femoral Artery Brand: Gore Viabahn Endoprosthesis With Heparin Model#: VBH101002A Cat #: VBH101002A	W. L. Gore and Associated, Inc.	Gore Viabahn 10mm x 10cm covered stent graft tracked to the left internal iliac artery aneurysm but would not track to the distal internal iliac artery. We then performed balloon angioplasty of the distal orifice of the internal iliac artery using a 7mm x 4cm balloon. We then tracked the Gore Viabahn 10mm x 10cm covered stent graft to the left internal iliac artery aneurysm but again it would not track to the distal internal iliac artery. At this point the Gore Viabahn partially deployed 2 rings of stent without pulling the trigger to deploy. This could not be re-captured within the sheath. We then removed this stent graft while deployed. Unfortunately, this caused trauma to the left iliac artery and left CFA.
Staple, Implantable Brand: Echelon Endopath Model#: GST60G Lot #: R4169K Cat #: GST60G Other #: Staple reload 60 Green	Ethicon Endo-Surgery, LLC.	Staple reload 60 Green had broken pieces in the staple reload package. When package was open on the back table. This occurred on the back sterile field and was not used on the patient /no patient harm
Needle, Hypodermic, Single Lumen Brand: BD Eclipse Model#: 305763 Lot #: 8207153 Cat #: 305763	BECTON DICKINSON AND COMPANY	Nurse sustained a dirty needle stick during an emergency IM injection to an agitated resident. Per nurse she activated the plastic safety glide over the needle and a portion of the plastic cover failed to cover the entire needle. She placed the used syringe onto her other hand and was pricked by the uncovered needle part. Department inspected 5 of these same needles, and found 2 out of the 5 were malfunctioning, when activating the plastic safety cover some were not covering the entire needle completely.

Links to FDA/CDRH Databases and Other Information Sources

Device Listing: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
This database contains a listing of medical devices in commercial distribution by both domestic and foreign manufacturers.

Establishment Registration: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
This is a searchable database of U.S. and foreign establishments engaged in the manufacturer, preparation, propagation, compounding, assembly, or processing of medical devices for U.S. distribution. Note: This database is updated once a month.

Human Factors Website: http://www.fda.gov/medicaldevices/deviceregulationandguidance/humanfactors/default.htm. This site provides information on human factors design, testing and use considerations for healthcare professionals, manufacturers and consumers.

Luer Misconnections Website:
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm
This site provides information for healthcare professionals about hazards that occur when different device delivery systems are mistakenly connected to each other facilitated by the use of Luer connectors.

MAUDE (Manufacturer and User Facility Device Experience): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM
MAUDE data represents reports of adverse events involving medical devices. The data consists of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996.

Medical Device Safety Website: http://www.fda.gov/medicaldevices/safety/default.htm
One-stop for safety information with links to published safety tips and articles, archived patient safety news programs, safety alerts, recalls, and a link to report a device-related problem.

MedSun Website: http://www.fda.gov/medsun/
This site provides patient safety information via current and past issues of the MedSun newsletter, educational materials, and search capability for MedSun adverse event reports.

Premarket Notifications [510(k)]: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
This database of releasable 510(k) s can be searched by 510(k) number, applicant, device name or FDA product code. Summaries of safety and effectiveness information are available via the web interface for more recent records. The database is updated monthly.

Premarket Approvals (PMA): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
This database of premarket approvals of Class III devices may be searched by a variety of fields and is updated on a monthly basis.

Product Classification: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
This database can be used to determine the classification of a device and the regulations it is subject to.

Warning Letters: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm
This database contains the most recent manufacturer warning letters.

To access additional March 2019 newsletter articles, including a selection of recent MedSun Reports and product-related and patient safety-related information, go to www.fda.gov/medsun

Contact the MedSun Program Staff:

Telephone: 800-859-9821
Fax: 800-859-1292
E-mail: medsun@fda.hhs.gov

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993