MedSun
Medical Product Safety Network

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

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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):
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/mda/mda-list.cfm?list=1

Premarket Approval Final Decisions:
https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/UCM591257.pdf

510(k)s Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm587897.htm

In Brief

As of February 5, 2018

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

AirLife Humidification Chamber, Heated Breathing Circuit Kits by Vyaire Medical: Class I Recall

January 31, 2018

Vyaire Medical recalled the AirLife Humidification Chamber and Heated Breathing Circuit Kits due to a manufacturing error that may cause parts of the chamber to split apart into layers, allowing water to overflow the chamber and to back up into the patient breathing circuit. If this occurs, an excessive amount of water could enter the airway or lungs of a ventilated patient and lead to serious adverse health consequences, including injury or death.

Zoll LifeVest 4000 Wearable Cardioverter Defibrillator: FDA Safety Communication

January 17, 2018

FDA is providing information and recommendations regarding the Zoll LifeVest 4000 due to concerns that the device may fail to deliver treatment to the patient if the device is not replaced soon after displaying "Call for service: Device has a problem that may require service. Call ZOLL for service, Message Code 102." Failure to contact Zoll and immediately replace the device after Message Code 102 appears on the device screen may result in serious patient harm or death of the patient because the device may fail to deliver therapy appropriately when needed.

Reprocessed Agilis Steerable Introducer Sheath by Sterilmed: Class I Recall

January 2, 2018

The Agilis Steerable Introducer Sheath’s hemostatic valve, which prevents blood from flowing back through the valve, may fail due to an improper seal of the sheath hub. Improper seals can allow blood to leak through the hub, cause the cap to fall off during the procedure, or can create a difference in pressure that allows air into the circulatory system (air embolism).

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during January 2018 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
Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days Brand: BD Nexiva, Bd Q-syte Model#: 383536 Cat #: 383536	Becton Dickinson and Company	Was asked to start IV for preop nurse. The patient had excellent veins. #20 gauge IV attempted x2 in right hand. There was no flash into the IV indicating I had hit the vein, however when removing the IV I pulled back the safety mechanism to retract the needle just to see. At that point a gush of blood came back into the IV, though before there was still no flash. The IV was removed. A third stick to the left hand was successful without any malfunction of the IV catheter. I mentioned this to the preop nurses that it just seemed strange what had happened, because the patient had great veins. At that point, I was told that there had been trouble previously with no flash of blood into the IVs. I said, that this was exactly what it felt like had happened. At this point, two PACU nurse managers were informed, and I asked that an email be sent out to staff to let them know if the trouble as I had not heard of any issues with the IVs previously.

Device	Manufacturer	Problem
Catheter, Intravascular, Diagnostic Brand: Er-reboa Model#: ER7232A Cat #: ER7232A	Prytime Medical Devices, Inc.	A 7F prelude sheath introducer kit was used to access the pre-existing left femoral arterial line. A floppy-tipped guide wire was passed through the arterial line, and the line was withdrawn over the guide wire. The 7F sheath with dilator were then passed over the guide wire into the femoral artery, and the dilator and wire were removed. A 7F ER-REBOA catheter was used to measure the distance from the patient's xiphoid to the left femoral arterial catheter site (40 cm), as well as the distance from the patient's umbilicus to the arterial catheter site (25 cm). It was then introduced through the sheath and advanced to 25 cm. The arterial line setup was connected to the distal port, and a 10cc syringe filled with normal saline was connected to the balloon port. Normal saline was slowly injected into the balloon port until pressure and pulsations were felt, which was after the 10cc. During this time, the BP was observed to slowly improve and stabilized with the systolic blood pressure at approximately 100, at which time the valve was closed. The REBOA catheter and introducer sheath were then secured to the patient's thigh with a silk suture and several strips of tape. The BP improved and stabilized, so then patient was taken from ED to CT. While in CT, the pt.'s BP then slowly decreased. I wore a lead apron and went into the scanner with the patient to interrogate the REBOA balloon as the CT C/A/P was continued. I found that the REBOA balloon was not holding pressure/ volume. I withdrew the syringe and aspirated blood from the balloon port. The MD noted that the balloon was not holding volume/staying inflated. The MD notes the clinical picture was consistent with a ruptured REBOA catheter balloon. The patient's BP persistently decreased, and the CT scan was aborted. The CT scan had shown the REBOA catheter was noted with its tip in the aorta, with the balloon desufflated, but noted in the mid-infrarenal aorta. The pt. was taken to surgery; shortly thereafter, the pt. went into asystole. CPR and internal cardiac massage was done, but he passed away. In the following days, the MD thought about it and the MD is unsure whether the REBOA failed or not; she feels it was leaking, but was questioning whether its placement was correct.
Electrode, Ph, Stomach Brand: Bravo Lot #: 36909Q	Given Imaging	The BRAVO ph capsule was attached to patient's esophagus for a 48 hour ph study after an esophagogastroduodenoscopy (EGD). When physician removed the applicator from the patient, the ph capsule was still attached to the applicator. The pin that holds the capsule to the esophagus was already deployed and could not be reused again in the patient. The capsule should have released from the applicator and stayed attached to the esophagus. The capsule then falls off after about a week.

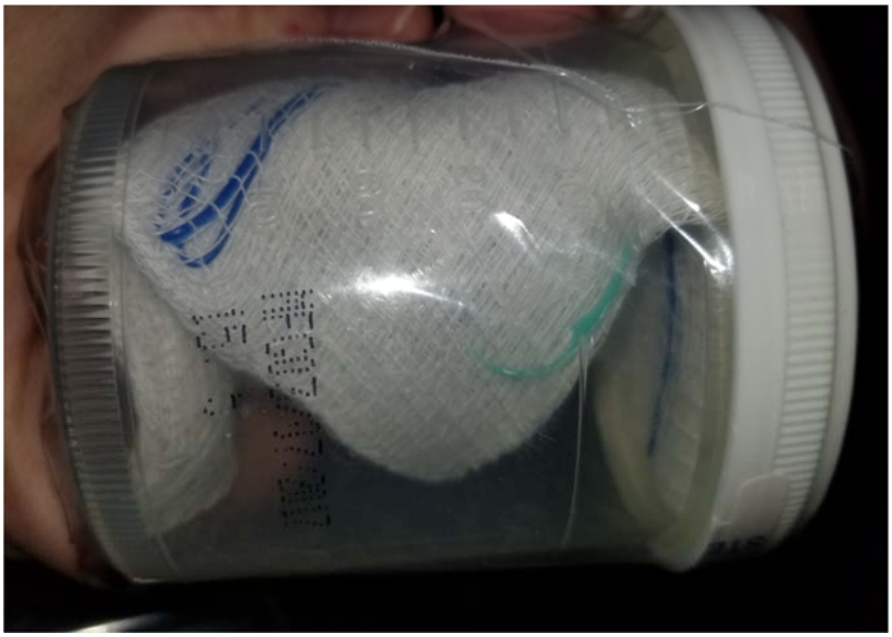
Device	Manufacturer	Problem
Device 1: Gas-machine, Anesthesia Brand: Aisys Model#: CS2 **Device 2: System, Network And Communication** Brand: Cerner Careaware Event Management Model#: Conectivity Engine	GE Healthcare Cerner Corporation	Patient was being operated on. While the patient was connected to the Anesthesia Machine, the Anesthesia Physician connected his USB phone charger to one of the outputs of the Cerner Connectivity Engine. This stopped HL7 data from flowing from the Anesthesia machine to the Cerner Medical record.
Heart-valve, Non-allograft Tissue Brand: Epic Cat #: E100-33M-00	St. Jude Medical, Inc.	A 33 mm St-Jude Epic mitral valve was implanted. But a hole was discovered on the valve after implantation. So the valve was removed and replaced by another another 33 mm St-Jude Epic mitral valve. The explanted valve was ordered to be sent to pathology for gross only, then to risk management, then to the OR materials management, and then to the vendor.
Holder, Head, Neurosurgical (Skull Clamp) Brand: Doro® Skull Clamp Model#: 3034-00 Other #: DORC Carbon Fiver Head Piece	Pro Med Instruments GmbH	Surgeon applied carbon fiber Mayfield head holder and the OR team positioned the patient prone on chest and hip bolsters. The positioning of the Mayfield holder was confirmed. It was tightened to 80 PSI. CAT scan was performed using the intra-operative scanner. Upon removal of the operative drapes, the surgeon identified that the Mayfield head holder had slipped. There was a scalp laceration in the left parietal area. It was repaired using Monocryl suture after cleaning the wound with Betadine solution. After flipping the patient supine, the surgeon inspected the patient's forehead for any abrasions or injuries. None were identified. Hard cervical collar was replaced. A cross-table lateral x-ray was used to investigate for any untoward movement of hardware. None was identified. There were no significant neuromonitoring changes from baseline. The carbon fiber head-frame was removed from service and given to Biomed for investigation.

Device	Manufacturer	Problem
High Level Disinfection Unit Brand: Trophon® Epr Model#: Trophon EPR	GE Healthcare	Patient diagnosed with localized prostate cancer presented to the Surgery Clinic for a surveillance prostate ultrasound. The patient was brought to the ultrasound suite and placed in the left lateral decubitus position. The ultrasound probe was then inserted into the rectum and serial transverse and longitudinal images were obtained. The prostate volume and the transition zone volume were calculated. The prostate and SVs were inspected for areas of hypoechogenicity, and a power Doppler exam was performed. The patient tolerated the procedure well and was released from the exam room uneventfully. During the QA review of the log associated with the Trophon machine used to disinfect the ultrasound probe used with Patient A, it was discovered that the high level disinfection cycle (HLD) following the previous procedure using the probe had failed. This suggested that Patient A was exposed to an ultrasound probe that had not been adequately disinfected. An error code DVF0020 was listed on the Trophon label associated with the failure cycle. After researching the error code and downloading the machine log files, it was determined the failure was due to the temperature not reaching the target value. The temperature during the disinfection cycle reached 55.6 degrees which did not meet the expected temperature minimum of 56 degrees. Since the other parameters were met, it was decided the probe was in fact adequately disinfected and posed no risk to the patient. The problem is when a cycle fails; it is easy for the operators to miss this fact since the only indication is on the small stickers printed by the machine. It would be better if there was a more obvious indicator of a failed cycle, such as the door staying locked until the operator acknowledges the load has failed. The operator may not be present when the cycle completes. It is also very difficult to view the log files from previous cycles. It requires a PC and proprietary software and cable. Error messages are not easily deciphered and we have to contact the manufacturer to interpret.
Holder, Head, Neurosurgical (Skull Clamp) Brand: Doro® Skull Clamp Model#: 3034-00 Other #: DORC Carbon Fiver Head Piece	Pro Med Instruments GmbH	Surgeon applied carbon fiber Mayfield head holder and the OR team positioned the patient prone on chest and hip bolsters. The positioning of the Mayfield holder was confirmed. It was tightened to 80 PSI. CAT scan was performed using the intra-operative scanner. Upon removal of the operative drapes, the surgeon identified that the Mayfield head holder had slipped. There was a scalp laceration in the left parietal area. It was repaired using Monocryl suture after cleaning the wound with Betadine solution. After flipping the patient supine, the surgeon inspected the patient's forehead for any abrasions or injuries. None were identified. Hard cervical collar was replaced. A cross-table lateral x-ray was used to investigate for any untoward movement of hardware. None was identified. There were no significant neuromonitoring changes from baseline. The carbon fiber headframe was removed from service and given to Biomed for investigation.

Device	Manufacturer	Problem
Laparoscope, General Plastic Surgery Brand: Aquas Powerflow Model#: 720-005-001 Lot #: I9213-D Cat #: 720-005-001	Genicon Inc.	Surgeon was using the AQUAS Genicon Powerflow suction irrigator (720-005-001) to irrigate an infected abdomen. The suction device leaked, sending pus filled fluid down the drape and into the surgeon's shoes. There have been several complaints from other staff and surgeons that this device is unsafe, as it leaks, and often the level of irrigation is highly forceful, causing splashes and potential contamination. This item is a substituted item due to the regular Stryker suction irrigator devices being unavailable due to the hurricane in Puerto Rico.
Monitor, Bed Patient Brand: Posey Products LLC Model#: 8309 Cat #: 8309	Hygia Health Services, Inc.	Patient who underwent hip repair surgery after a fall with fracture late last year. Three days later, while in the hospital she was returned to her room from physical therapy. A staff member walked by her room and saw the patient on the floor. The Posey chair alarm appeared to be on, but was not alarming. The staff did not remove this alarm pad or alarm box from service. The patient sustained a fracture to the hip and required surgery. She is currently in rehabilitation. We are unable to provide the product to the manufacturer for investigation. We have contacted the Rep to make them aware.
Neurosurgical Paddie Brand: Surgical Patties Cat #: 80-1407	Codman and Shurtleff, Inc.	A patient presents to the OR for a Le Fort 1 osteotomy. After initial incision near the gumline, cottonoids followed by gelfoam were packed into the patient's mouth to control bleeding. Once the gelfoam and cottonoids were saturated, they were removed often by pulling on the cottonoid identification string and handed to the surgical technician. New cottonoids and gelfoam were then added. During removal of a set of foam and cottonoids, the surgical technician notified the team that they had received a string containing fibers at one end, but no cottonoid attached. The surgeon performed a brief search for the missing cottonoid, then opted to continue the case with the plan to get an x-ray to look for the cottonoid. The cottonoid was missed on x-ray, and the patient was returned to the OR two days later to retrieve the retained cottonoid. General concern: The design of the "identification string" predisposes clinicians to misusing the string as a means to remove the cottonoid, which could result in breaking of the string or shearing of the cottonoid when being removed from the patient.
Pump, Infusion Brand: Walkmed 350vl	WalkMed, LLC	The patient returned to the outpatient clinic as the home infusion they had been receiving had completed and that is what displayed in the window of pump "end". This "completed" in the timeframe expected. Assessment of the pump found that none of the infusion/IV had infused during the given time. It was discovered that inadvertently the pharmacy had left a clamp on the tubing. If worked as designed, the infusion pump should have stopped and displayed error when no fluid was going through the system. Instead the pump acted as if it were actively infusing, then "end" when completed.

Device	Manufacturer	Problem
Pump, Infusion, PCA Brand: Cadd Solis Model#: 2110	Smiths Medical MD, Inc.	Patient was undergoing PCA delivered pain management when pump alarmed Reservoir Volume is zero. The reservoir used on these pumps are dosed and delivered with 100ml medication. When clinician removed cassette form pump she noted reservoir almost full. Following establish workflow the RN contacted Pharmacy to have contents measured. Remaining volume found in the reservoir was measured at approx. 70ml with 5-10 ml remaining in reservoir cassette. Pump and cassette sent to Biomedical engineering for analysis and reporting. Biomedical downloaded the event log from the pump and noted the time that the cassette was attached to the pump (04:51 AM) and when the cassette was remove approx. 9 hours later (1:59PM). Biomedical reviewed the event log for this time period and noted that the volume the pump delivered matched the pumps programming of 0.4mg/hr dosing and PCA dose of 0.4m of 0.1mg/ml Dilaudid-HP. The pump delivered 15 PCA doses 6.0mg) and approx. 3.6mg of drug to give a final volume of greater than 95 ml. Biomedical prepared pump for manufacturer evaluation and analysis. Biomedical will provide the mfg. with pump and cassette used in this delivery in order to test devices together. This is a re-occurring event involving this model pump at our facility.
Ventilator, Continuous, Facility Use Brand: Enve Ventilator Model#: 19250-001 Other #: Operations Meter: 32466.2 hours	Carefusion	Patient on full ventilator support. When the respiratory therapist (RT) was in the patient's room during rounding, RT heard the patient's ventilator functioning. The RT began to document numbers; the vent screen went blank and the vent was not alarming. RT observed that the vent was not triggering breaths and the patient was not breathing. The RT immediately intervened by disconnecting the vent and the patient was bagged while another RT brought in a new vent. The vent never did alarm. The patient never dropped Sp02 and was never in harm because the RT was in the room at the time the vent malfunctioned. The vent was removed from service and brought to the Biomedical Engineering Department. The ventilator was sent to the manufacturer for inspection.
Automated External Defibrillators (Non-wearable) Brand: Onestep Model#: 8900-0221-01	Biodetek Incorporated	Defibrillator pads were not adhering to skin. We removed the set of pads and discovered gel had migrated and congealed in clump to center of pad and silver packing was exposed to patient's bare skin. This had happened on both defibrillator pads on same set. Pads had been placed on the patient prior to patient going to OR and the set of defibrillator pads were on the patient for less than 24hrs. We saw this same defibrillator pad gel clump into one spot on another set of defibrillator pads used for another patient. Two occurrences two different defibrillator pads used on two different patients within 48 hours. Staff did not keep packaging so do not know lot number or expiration dates.

Device	Manufacturer	Problem
Syringe, Irrigation Brand: Bard® Bulb Irrigation Syringe Cat #: 0035280	C. R. Bard, Inc.	EP Physician was creating a skin pocket for the insertion a pacemaker. Part of that process is to use a 50cc bulb-type syringe to irrigate the newly created pocket. As he was completing the final inspection of the pocket, the EP Physician noticed a 2 to 2.5 cm long very thin sliver of green plastic or rubber sitting in the bottom of the skin pocket. It appears to be from the bottom edge of the green bulb which sits inside the syringe portion of the bulb-syringe device. When I look through the clear plastic of the syringe portion, I can see that the neck edge of the green bulb it not smooth. Part of the bulb still has a rough edge remaining and attached. It's very apparent that the selvage edge at the neck of the bulb was where the green sliver broke off and the sliver was propelled into the skin pocket during the irrigation process. To my eye, the sliver which broke off seems to be a by product of the manufacturing process. There was no harm to the patient and the sliver was quickly removed. I have both the bulb syringe and the green plastic/rubber sliver which was retrieved in my office. I have already contacted the company rep so they can send me the box to return the items to the company. Please see pictures below: 

Device	Manufacturer	Problem
Syringe, Irrigation Brand: Bard® Bulb Irrigation Syringe Cat #: 0035280	C. R. Bard, Inc.	
Replacement Heart-valve Brand: Carpentier-edwards Perimount Magna Ease Pericardial Bioprosthesis - Aortic Model#: 3300TFX Lot #: 863964002 A Cat #: 3300TFX27MM	Edwards Lifesciences, LLC.	The LifeSciences Aortic valve was opened and prepared for implantation. On close inspection it was found to have stitching that had come loose and the surgeon did not wish to use the valve. The defective valve was not implanted. We have the valve here at the hospital if the company wants to have it returned.
Set, Administration, Intravascular Brand: Alaris Model#: 30893-07 Lot #: 11611800 Cat #: 30893-07		PCEA intiated in the OR by anesthesiologist. After starting the PCEA, it was identified there was a leak in the tubing and medication was not reaching the patient. Tubing was changed with appropriate delivery of medication. Leak located just distal to the pump. When the pump was started, tubing was wet and changed immediately. No impact to the patient.

Device	Manufacturer	Problem
Stimulator, Autonomic Nerve, Implanted For Epilepsy Brand: Vns Therapy® Sentiva™ Model 1000 Generator Model#: 1000 Cat #: GMDN 34210	LIVANOVA USA, INC.	The patient had a vagal nerve stimulator battery replaced in surgery. After the patient was taken to her room for post-care, the nurse noted that the newly replaced battery showed message which stated: "EOS- End of Service". The Neurosurgeon was notified and the patient was scheduled to replace the battery once again. The manufacturer's representative was in surgery during the battery placement.

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 February 2018 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:

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Food and Drug Administration
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