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):

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 September 30, 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

Vyaire Medical, Inc. Recalls Tri-Flo Subglottic Suction System Due to Risk of Device Breakage

September 4, 2018

Vyaire Medical, Inc is recalling the Tri-Flo Subglottic Suction System because there is a risk that the distal soft tip of the catheter may break off and enter the patient's lungs. This may result in serious adverse health consequences including choking, wheezing, additional surgery to remove the tip from the patient's lungs, irritation and reddening of the skin (erythema) of the airways, infections or death.

Compass Health Brands Recalls CPAP Mask Cushion Devices Due to Possible Air Leaks

August 31, 2018

Compass Health is recalling the replacement cushion seals for the Probasics Brand Zzz-Mask SG Full Face CPAP Mask due a design change made to the cushion seal replacement part and accompanying elbow replacement part that causes the seal to be incompatible with the mask. While no complaints or injuries have been reported, the use of the new cushion with the previous design of the mask could result in an air leak that interrupts therapy.

Temporary Total Artificial Heart Companion 2 Driver System by SynCardia Systems: Letter to Health Care Providers

August 17, 2018

FDA has reviewed the final results from the post-approval study conducted by SynCardia Systems for their Temporary Total Artificial Heart (TAH-t) Companion 2 Driver System (C2 Driver System). These final results indicate a higher mortality rate and higher stroke rate for patients initially supported with the C2 Driver System compared to patients initially supported with the previous generation driver, the Circulatory Support System (CSS) Console.

FREE FDA Webinar:

Hospitals, Manufacturers and FDA Partnering on Duodenoscope Reprocessing Safety – 1 CE Credit

October 3, 2018

1 PM - 2 PM Eastern Time
12 PM - 1 PM Central Time
11 AM - 12 PM Mountain Time
10 AM - 11 AM Pacific Time

Target Audience:

- Staff working in endoscopy reprocessing units in health care facilities;
- Infection control practitioners;
- Facility risk managers;
- Endoscopy nurses;
- Gastroenterologists;
- Gastrointestinal surgeons.

Is your healthcare facility interested in assessing the duodenoscope reprocessing practices in your hospital? Would you like to partner with FDA and scope manufacturers to address the public health concern of infections associated with contaminated scopes? Would you like to participate in an ongoing study that is designed to evaluate the real-world effectiveness of duodenoscope manufacturers' reprocessing instructions? If so, you'll want to participate in the upcoming FDA webinar. This webinar may be of interest to infection control practitioners and other healthcare professionals from facilities where Endoscopic Retrograde Cholangio-Pancreatography (ERCP) procedures are performed.

FDA Presenters:

Lauren J. Min, PhD, obtained her graduate degrees from Johns Hopkins University and University of Pittsburgh. In 2011, Dr. Min joined the FDA's Center for Devices and Radiological Health as an epidemiologist in the Office of Surveillance and Biometrics. Dr. Min currently is the lead reviewer for post-market surveillance studies of duodenoscope reprocessing.

Shani Haugen, PhD, is a microbiologist at the FDA's Center for Devices and Radiological Health in the Office of Device Evaluation. She evaluates the safety and effectiveness of reprocessing instructions for gastrointestinal endoscopes. Dr. Haugen worked with the Centers for Disease Control and Prevention (CDC), the American Society for Microbiology (ASM), duodenoscope manufacturers, and other experts to develop a validated protocol for surveillance sampling and culturing of duodenoscopes.

CE Credit: The US Food and Drug Administration, as a provider approved by the California Board of Registered Nursing, Provider Number CEP 16323, grants 1 contact hour of Continuing Education credit for this program. The certificate for CE credit will be sent once we receive the responses to a brief evaluation form.

Recording: The program will be recorded for those who are not available for the live session. The link to the recording will be provided to all who indicate interest in the program (for their use and for others in their hospitals/healthcare systems as well).

To Indicate Interest: Please e-mail medsun@fda.hhs.gov, attention '10/3 Webinar', and include your name, email address and phone number. Please indicate interest even if you are not sure of your availability for the live webinar.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during September 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
AED Pads	Zoll	Upon attaching AED pads to patient during Code Blue, one of the pad wires were detached therefore causing the pad to not work. This caused a delay in critical care for the patient as a second set of pads were sought after. No harm to patient. Those present believed the defect was not realized until pad packaging was opened as it was an internal issue within sealed packaging. Biomed received faulty pads and is starting a conversation with the vendor and their QC team to be sure this is not an issue within other packages of pads that we have. It is possible that the wire was torn upon opening the packaging but is not clear yet. There is always 2 sets of pads on the code carts as a back up. In this case, there were two on the cart so the team was able to open the second pair and perform the shocks needed.

Device	Manufacturer	Problem
Cannula, Manipulator/ Injector, Uterine Brand: Vcare- Model#: 60-6085-201A Lot #: 201805011 Cat #: 60-6085-201A	ConMed Corporation	It was reported to clinical engineering that ConMed VCARE Medium was opened to the sterile field. Doctor went to test the balloon and it had a hole in it. Device taken off the sterile field and placed in soiled utility for pickup. No harm came to the patient and the device will be returned for failure analysis.
Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System Brand: Tevadaptor® Luer Lock Adaptor Model#: MG412114 Cat #: MG412114	TEVA PHARMACEUTICAL INDUSTRIES LIMITED	Both CSTD components became disconnected along with the CareFusion needle free valve (injection cap) that we use. The line became disconnected leaving the central line open and bleeding out. The patient was discovered because bed alarm went off. There have been several other disconnects where the CSTD disconnects from the tubing and we are waiting on a product update to fix that issue.
Cold Therapy Kit Brand: Jetstream Cold Therapy Kit Model#: T700	DeRoyal Industries, Inc.	The device is leaking at the connecting hose. Several of these kits have been returned for the same reason. The patient had to return to the hospital for a new kit.
Dialysate Concentrate For Hemodialysis (Liquid Or Powder) Brand: Nxstage Pureflow BSolution Model#: RFP-401 Lot #: Q1803828	NXSTAGE MEDICAL, INC.	Nursing is reporting several instances of continuous renal replacement therapies (CRRT) bags bursting. In one report, the nurse wrote, "We have had multiple NxStage CRRT bags break open while popping them for use. In this particular incident the spill attributed to a family member falling." In another report, the nurse wrote, "I was attempting to mix the dialysis bag to place on the CRRT machine. When attempting to mix the dialysis solution the bag split open on the edge, when it should have opened inside of the bag to allow the electrolytes mixing with the solution. When it split open, the smaller portion of the bag containing the K+ ruptured with enough force to soak the front of my shirt, spray my face and get all over the floor. It was not enough for it to happen once, but the very next bag did the same thing. After I went home I noticed I had what appeared to be a mild chemical burn to both breasts where the solution soaked into the bra. I equate it to a medium sunburn."

Device	Manufacturer	Problem
Arthroscopic Shaver Blade Brand: Stryker Arthroscopic Shaver Lot #: 18113CE2 Cat #: 0375-544-000	Stryker Endoscopy	Staff opened a brand new arthroscopic shaver and while taking it out of the cannula, fluid came out. The device was not used on the patient, it was caught prior to start of the case.
Humidifier, Respiratory Gas, Interface Model#: AIRVO 2	Fisher & Paykel Healthcare, Inc.	While connected to a patient, the device stopped delivering flow. The only flow felt was what was dialed in on the flowmeter. There was no heat coming out the other end, and no visual or audible alarm. Tried turning off and turning back on but that did not help.
Implant, Cochlear Brand: Nucleus Freedom Cat #: C124RE (CA) Other #: nucleus C124RE 005 102 cochlear Australia 167787 	Cochlear Americas	The child has binaural profound sensorineural hearing loss. She had cochlear implant placed in the right ear five years ago. Patient had a visit with primary care physician two months ago for persistent pain, bleeding from right ear, and a foul smell with whitish discharge. MD notes: right ear canal with erythema and bloody purulent discharge and debris. Tympanic membrane is erythematous. The left tympanic membrane is clear. Cochlear implants in place. Given ciprofloxacin-dexamethasone otic, four drops to right ear two times a day for seven days with referral to ENT doctor. Patient seen by ENT specialist. He notes that on assessment he sees an electrode in the right middle ear space through monomer. The right ear has an electrode in the canal. It apparently eroded through. Subsequently, the patient to the OR and found eroded lead wire of cochlear implant with tympanic membrane perforation and canal wall erosion. Per op note: The electrode had eroded through the posterior superior aspect of the canal, almost fully lateral. Then, the electrode had eroded through the posterior superior tympanic membrane. Performed removal of cochlear implant with tympanoplasty. Plan was to leave the electrode in the cochlea, but remove the rest of the device and allow the ear to heal.
IV Fluid Administration Set Brand: Level 1Normothermic Iv Fluid Administion Set Lot #: 3179924 Cat #: D-100	Smiths Medical ASD INC	During Massive Transfusion Protocol, RN initiated infusion of PRC cells via Rapid Infuser and immediately noticed leaking from where blood bag was spiked. Infusion stopped and new IV Infusion Set of different lot number primed and utilized with no problem.

Device	Manufacturer	Problem
Mobile Patient Transfer/ repositioning Device Brand: Prevalon Airtap Model#: 7450 Cat #: 7450	Sage Products LLC	Staff went to use this device and they turned it on and as they moved it they noticed a spark/arc where the power cord meets the device. The arc occurred because the power cord has made it way far enough out of the power receptacle even though the power cord bracket was in place.
Monitor, Bed Patient Brand: 14-day Sensormat Pad Model#: 73030 Other #: B0817	Stanley Security Solutions, Inc.	Elderly male with confusion/disorientation had fall-precautions in place. Patient got up to go to the bathroom and chair alarm did not go off (set as alarmed and activated under patient). Tested and still did not work, so a new one was set up and tested ok. Patient sustained 4 skin tears to left arm, bruise/contusion. Fall Precautions include the following in place at time of fall: • Bed in low position • Bed Table in reach • Call Bell in reach • Call Light/phone/bedpan/pother personal items in reach • Caution Signs in place • Chair Alarm • Fall Alert • Hourly (or more frequent) Comfort and Toileting rounds • Light/Night Light on • Non-Slip Footwear • Patient Family Education • Patient Situated Close to Nurse's Station • Physician/Occupational Thx • Use of Gait Belt

Device	Manufacturer	Problem
Port, Catheter, Implanted Brand: Power-port Clearvue Isp Implantable Port Model#: 1608052 Lot #: RECR2215 Cat #: 1608052	Bard Access Systems, Inc.	The physician went to attach the PowerPort to the tubing and the part that slides into the tubing just fell off into three pieces.
Transfer Aid Brand: Gait Belt Model#: DYKF1045 Cat #: DYKF1045	Medline Industries, Inc	The gait belt clasp came undone while staff were assisting patient to stand from chair. The clasp unbuckled, patient's knees buckled, and staff lowered patient to the floor. The RN checked another gait belt in the fall bags, and noted it too did not stay closed when staff pulled on it.
Ventilator, Continuous, Facility Use Brand: Edi Catheter Model#: 6685775 Cat #: 6685775 		Premature infant delivered due to fetal distress and premature rupture of membranes. Patient intubated at delivery and surfactant given. On DOL (day of life) #2, neurally adjusted ventilatory assist (NAVA) technology initiated w/ 6 Fr. electronic diaphragm monitoring (EDI) catheter placement. EDI catheter length = 49cm. On day of life (DOL) #3, the catheter was advanced by the nurse to 14cm per "vent notification." Per report of staff, vent feedback was appropriate, and the catheter was left at 14 cm. On DOL #8, the EDI catheter was exchanged per manufacturer guidelines (change every 5-7 days). The new catheter was inserted to distance of 14cm as previous and catheter placement was confirmed. On DOL #9, the RN noted the EDI catheter was at 15cm. The nurse noted that placement was confirmed with auscultation and ventilator feedback. On DOL #10, the infant had desaturations and was noted to have a tense and erythematous abdomen. The endotracheal tube was confirmed in good position. X-ray of the abdomen revealed free air. Surgery was consulted; a Gastrografin study revealed the catheter was seen intra-peritoneally. The catheter was removed. A laparotomy was performed with drain placement to decompress the abdomen. Noted concerns reported by Neonatology: 1) The medical team had no reason to believe the catheter was in wrong based on the feedback from the ventilator, which is how the representative from the company instructed the team to monitor placement. 2) The catheter measured deeper than in previous days, but diaphragmatic activity was still picked up by the ventilator which led team to believe tube was where it needed to be. 3) Concerns regarding education provided by company to medical providers regarding repositioning the catheter and recognizing when it is possibly out of place.

Device	Manufacturer	Problem
Transcatheter Septal Occluder Brand: Gore Cardioform Septal Occluder- Model#: GSX0025A Cat #: GSX0025A	W.L.Gore & Associates, INC	INTERVENTION: Device closure of secundum atrial septal defect. Cefazolin 510 mg was administered IV. 1. Flow occlusion diameter. An 18 mm Amplatzer sizing balloon was prepared in the usual fashion. A 035 superstiff wire was positioned antegrade across the atrial septal defect into the left upper pulmonary vein using a 7 French wedge catheter. the wedge catheter and 7 French femoral venous sheath were removed and exchanged for a 10 French short sheath. The sizing balloon over the 035 wire through the skin. The prepared balloon was further de-aired in the right atrium. It was then positioned across the atrial septal communication and inflated until flow occlusion was demonstrated by transesophageal echo. A nice central waist was demonstrated and flow occlusion balloon diameter was 11 to 12 mm. The sizing balloon arid superstiffwire were removed without difficulty. 2. Closure of secundum atrial septal defect. It was elected to use a Gore Cardioform 25 mm device, based on the septal size and flow occlusion diameter. The device was inspected and appeared intact. It was flushed with saline and loaded into the delivery system using standard protocol. The loaded device was transferred through the 10 French femoral venous sheath using standard protocol and advanced into the right atrium. The sheath was then advanced into the left atrium using transesophageal echo guidance. The left disc was performed and the whole system brought towards the atrial septum. The left disorientation was perpendicular to the defect. The left disc was then manipulated so that it aligned better along the atrial septum and the right this was opened on the right atrial side. There was significant tension on the atrial septum but the device position appeared appropriate with no shunting at the margins of the device. It was elected to lock the device to allow it to reorient appropriately. The device was locked without difficulty. There was significant reorientation And better device position and alignment. Transesophageal ECHO demonstrated that the device was in appropriate position with no shunting at the margins of the device. All the rims appear to be adequately captured. The device was completely released by removing the attaching thread. Once this was performed Transesophageal echo demonstrated that the inferior portion of the device has slipped so that both discs appeared to be in the left atrium. The device was still stable. However it was it was continue to observe the device was slipping further into the left atrium. It was therefore elected to attempt retrieval. As we were attempting to capture the device the device slipped into the left atrium and was across the mitral valve. While we were trying to get appropriate catheter position the device further embolized into the ascending aorta. Cardiothoracic surgery team was called. Using a 7 French wedge catheter and a JR5 catheter a wire was advanced antegrade into the left carotid artery However it was difficult to advance any retrieval device due to the catheter course. A 6 French sheath was placed in the right femoral artery to attempt retrograde retrieval of the device. The cuff blood pressure and the femoral arterial pressures were low. Patient had sinus rhythm but started to develop sinus bradycardia. External compressions were started. Attempts were made to try to retrieve the device retrograde.

Device	Manufacturer	Problem
Transcatheter Septal Occluder Brand: Gore Cardioform Septal Occluder- Model#: GSX0025A Cat #: GSX0025A	W.L.Gore & Associates, INC	This included trying to grab the device with a Rat tooth forceps through a 6 French guide catheter. However the guide catheter tip was not strong enough to adequately direct the rat tooth. The short 6 French sheath was exchanged for a curved long 6 French sheath. A descending aortogram was performed through the long 6 French sheath. This demonstrated that the device was lodged in the distal portion of the ascending aorta and 1st part of the transverse aorta. The long sheath was positioned in the ascending aorta to at least created pathway for blood to low across the device. With cardiac compressions and motion it was difficult to visualize the exact orientation of the device. A 12 mm diameter balloon was prepared in the usual fashion and advanced over the 018 wire through the 6 French sheath and into the ascending aorta proximal to the device. The balloon was inflated and the whole system pullback to see whether the device could be further dislodged and migrated into the descending aorta to facilitate removal as well as blood flow to the carotid arteries. Despite significant force the device would not dislodge or move. The balloon was deflated and removed intact. Cardiac compressions were continued. The cardiothoracic surgical team was in position to perform emergency surgery.
Ventilator, Continuous, Facility Use Brand: 840 Ventilator Model#: 840 Other #: Puritan Bennett	Covidien	Puritan Bennett 840 Ventilator began to alarm, "Safety Valve Open". Nurse heard the alarm, and began to ventilate the patient via ambu bag. Respiratory therapist was notified, and subsequently exchanged the ventilator. No adverse reactions noted.
Ventilator, Emergency, Powered (Resuscitator) Brand: Pneupac Vr1	Smiths Medical ASD, Inc.	Pneupac VR-1 stops ventilating patient when oxygen tank runs out, no alarm or other trigger to alert team.

Device	Manufacturer	Problem
Device 1: Blade, Saw, Brand: Integra Dermatome Blade Model#: PAD3539-252 Lot #: 111000322298 Cat #: 3539-252 **Device 2: Dermatome** Brand: Zimmer Air Dermatone Model#: 00-8801-001-00 Cat #: 00-8801-001-00	STERILMED, INC. Zimmer Orthopaedic Surgical Inc	Zimmer Dermatome hand piece was used with an Integra Dermatome blade for skin graft procedure which caused patient injury. Zimmer blade is to be used only with the Zimmer hand piece however Integra blade fits into Zimmer hand piece, additionally the Zimmer blade and Integra blade look similar, packaged similarly and they were stocked in the OR in the same location. To note the Zimmer blade does not fit into the Integra handle. Large open wound created. Skin graft procedure was completed.
Staple, Implantable Brand: Proximate Cat #: TLC75	Ethicon Endo-Surgery, Inc.	Patient was having an EGD with dilation of stricture in endo this morning and suffered a perforation. Surgeon took him to the OR for an exploratory laparotomy. We did that and resected the portion of bowel that had been damaged during perforation. We used the Ethicon 75mm blue linear cutter stapler (Reference number TLC75) with two reloads. Surgeon reported the staple line continued to bleed and required over sewing with suture to achieve hemostasis with no sign of leakage. The surgeon stated his frustration with the quality of the stapler/cutter several times during the surgery, and he feels this inferior product is a very concerning patient safety issue that places the patient at an increased risk for leaking and bleeding at anastomotic sites.
Device 1: Set, Administration, Intravascular Brand: Alaris BD Model#: 30893-07 Lot #: 17096980 Cat #: 30893-07 **Device 2: Set, Administration, Intravascular** Brand: Alaris BD Model#: 30893-07 Lot #: 17096818 Cat #: 30893-07	CAREFUSION 303, INC. CAREFUSION 303, INC.	Epidural placed, immediately noticed leaking tubing at connector hub. MD notified, replaced tubing. Tubing not saved by staff. Affected lots per supply chain management: Lot # 17096980, Exp 9/29/2020 Lot # 17096818, Exp 9/28/2020 x2

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 October 2018 newsletter articles, including a selection of recent MedSun Reports and product-related and patient safety-related information, go to www.fda.gov/medsun

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Food and Drug Administration
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