

About the MedSun Program

The MedSun Program, which was launched in 2002 by the 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 reporting system for reporting problems with the use of medical devices. MedSun plays a critical role in FDA's postmarket surveillance efforts.

If you are interested in having your healthcare facility join MedSun, contact medsun@fda.hhs.gov for additional information or see <http://www.fda.gov/medsun> for details.

As of 08/31/2022

Class I Recall: [North American Diagnostics Recalls Oral Rapid SARS-CoV-2 Rapid Antigen Test Kits That Are Not Authorized, Cleared, or Approved by the FDA](#)

08/01/2022

North American Diagnostics is recalling tests because they were distributed to U.S. customers without authorization, clearance, or approval from the FDA. North American Diagnostics did not provide the FDA with adequate validation data to show that the test's performance is accurate. This means there is a risk of potential false negative, false positive, or misinterpretation of results. Use of these tests may cause serious adverse health consequences or death.

Class I Recall: [Haimen Shengbang Laboratory Equipment Co. Ltd. Recalls Viral Transport Media Containers That Are Not Authorized, Cleared, or Approved by the FDA](#)

08/08/2022

Haimen Shengbang Laboratory Equipment is recalling Viral Transport Media Containers because these products were distributed to U.S. customers without authorization, clearance, or approval from the FDA. This means there is a risk for false negative, false positive, or misinterpretation of results if these products are used to detect SARS-CoV-2. Use of these products may cause serious adverse health consequences or death.

Class I Recall: [Becton Dickinson Recalls Intraosseous Needle Set Kits, Intraosseous Manual Driver Kits, and Intraosseous Powered Drivers for Issues That May Cause Delayed Treatment Delivery](#)

08/11/2022

Becton Dickinson is recalling the BD Intraosseous Needle Set Kits, BD Intraosseous Manual Driver Kits, and BD Intraosseous Powered Drivers for three separate issues:

- The stylet may be difficult to separate from the needle or may not separate at all.
- The needle safety mechanism may not properly deploy as the stylet is removed from the intraosseous needle after placement.
- Metal discs may stick in the powered driver, which may render it unusable.

These issues can cause delays in care due to the inability to place functional intraosseous access. Since intraosseous access is most often used in critically ill patients, including those with cardiopulmonary arrest or severe shock, the potential delays in care can cause serious injury or death.

Class I Recall: [Covidien, LLC \(Medtronic\) Recalls Palindrome and Mahurkar Hemodialysis Catheters Due to Catheter Hub Defect](#)

08/18/2022

Covidien, LLC (Medtronic) is recalling the Palindrome and Mahurkar catheters due to a catheter hub defect that will connect both extension catheters. There is a potential leaking condition within the hub of specific chronic dialysis catheters. This may be noticed when flushing one extension tube and the flow of fluid through the tip of the catheter returns unanticipated fluid through the adjacent extension tube. During treatment, this leak could result in mixing of the arterial and venous blood and lead to increased recirculation and poor dialysis, and the development of thrombi and emboli. The use of the defective catheter may cause serious adverse health outcomes, including bleeding, surgical removal and replacement of the affected catheter.

Class I Recall: [Medtronic Recalls Cobalt XT, Cobalt and Crome ICDs and CRT-Ds for Risk that Devices May Issue a Short Circuit Alert and Deliver Reduced Energy Shock During High Voltage Therapy](#)

08/19/2022

Medtronic is recalling Cobalt/Crome Implantable Cardioverter Defibrillators (ICDs) and Resynchronization Therapy Defibrillators (CRT-Ds) after receiving reports of devices with a short circuit protection (SCP) alert resulting in reduced-energy electric shock delivery, instead of delivering a second phase of high voltage therapy. A reduced-energy electrical shock may fail to correct an irregular heartbeat (arrhythmia) or may cause an irregular heartbeat. The harms associated with a reduced-energy electric shock or an inaccurate response to an SCP alert may cause serious injury or death.

Class I Recall: [Medtronic Recalls HeartWare HVAD System Batteries for Electrical Faults That Cause Battery Failure](#)

08/25/2022

Medtronic, Inc. is recalling HeartWare HVAD System batteries because the batteries may experience electrical faults that cause them to unexpectedly fail. When this occurs batteries with an electrical fault may be unable to power the controller, unable to accept charge from the battery charger, or appear to remain charged when in use. If the battery fails and the patient is unable to replace the failed battery with a charged, working battery or with AC or DC power, the HVAD may stop working, leading to serious injury or death. Medtronic reports 1,159 complaints, six injuries, and one death related to this issue.

Class I Recall UPDATE: [Medtronic HeartWare Ventricular Assist Device \(HVAD\) System](#)
UPDATE 08/25/2022

On 06/03/2021, Medtronic stopped the sale and distribution of the HeartWare Ventricular Assist Device (HVAD) system given the increased risk of mortality and neurological adverse events in patients using the device, and a malfunction where the device may fail to restart. Both problems may lead to serious injuries or death. FDA continues to work with Medtronic to ensure the health and safety of device users, which remains our highest priority. This includes ensuring current patients continue to receive appropriate follow up monitoring and Medtronic continues to meet its obligations to support patients and health care providers. FDA is committed to providing important updates about the HeartWare device and we will continue to update the public as new information becomes available.

- Recommendations were added to the [Information for Patients and Health Care Providers: HVAD System section](#) about useful life and inspections for HVAD System components.
- The FDA [Activities Related to HVAD System](#) table was updated to include the FDA's Class I recall notice for the June 2022 recall related to the increase in battery electrical faults due to an interaction between the battery software and an internal component.
- Medtronic issued an Urgent Medical Device Correction to inform health care providers that they will begin exchanging HVAD power sources (batteries, AC and DC adapters) and Monitor data cables with newly designed components. Medtronic also identified that the device labeling has been updated with information regarding useful life and inspection of HVAD System components. This update has been added to the [Medtronic HeartWare Recalls](#).

Class I Recall [Intera Oncology Recalls Intera 3000 Hepatic Artery Infusion Pump Due to Faster Than Expected Flow Rates That May Impact Infusion Delivery](#)

08/29/2022

Intera Oncology is recalling the Intera 3000 Hepatic Artery Infusion Pump after receiving reports from clinicians that the pumps were delivering medications (flow rate) faster than expected. If the pump delivers infusions at faster than expected flow rates, the patient may receive too much medication at one time, resulting in life-threatening hematologic (myelosuppression) toxicity, neurotoxicity, or death. Additionally, if the flow rate is too fast, the patient may run out of medication before a pump refill occurs, which may allow their disease to progress or lead to death. There have been three incidents reported related to this issue, with no injuries or deaths.

Class I Recall [Hamilton Medical AG Recalls Hamilton-C6 Intensive Care Ventilator Due to Potential Water Ingress that May Cause Breathing Support to Stop](#)

08/29/2022

Hamilton Medical AG is recalling the HAMILTON-C6 Intensive Care Ventilator after customer complaints revealed a hardware issue with the ventilator's status indicator board. The status indicator board may become loose, allowing liquid to enter (ingress) between the indicator board and the ventilator's main board. This water ingress may cause the ventilator to have a technical fault and revert to a safety ventilation mode or revert to an ambient state, which means the patient breathes ambient room air with no assistance or support from the machine. When the ventilator enters ambient state, an alternative source of ventilation must be provided immediately or the patient may

buildup of carbon dioxide in the blood (hypercarbia), other serious injuries, or death.

MedSun Webcast Orientations

We're providing you a schedule of upcoming MedSun Webcast orientations. These may be of interest to Lead MedSun Representatives who would like to add or change a reporter. If you would like to orient a new reporter in your hospital, please send your request to your FDA MedSun Representative or contact us at MedSun@fda.hhs.gov or 800-859-9821.

1:00 PM to 2:00 PM Eastern Standard Time (12:00pm CST/11:00am MST/10:00am PST)	
Thursday	September 1, 2022
Tuesday	October 4, 2022
Thursday	November 3, 2022
Tuesday	December 6, 2022

UPDATE- 08/17/2022: [Stop Using Certain Syringes and Needles with Needle Safety Devices Manufactured by Haiou – Letter to Health Care Providers](#)

In June 2022, Guangdong Haiou Medical Apparatos Co., Ltd. Initiated a voluntary recall of the HAIYOU Needle Retractable Safety 1 mL syringe with [23G 1-inch needle](#) and the HAIYOU Needle Retractable Safety [1 mL syringe with 25G 1-inch](#) needle for device failure.

The affected needles and needle holders may detach from the syringe after injection and the needle may remain in a patient's arm, resulting in an increased risk of needle stick injury to the end user. Any unused product should be removed from distribution and inventory.

[FDA recommendations](#) have not changed. FDA will keep the public informed if significant new information becomes available.

Safe Medical Device Act Requires Reporting of Certain Events

Because the hospital's insights are so important to making sure that medical devices are safe and effective, some problems with medical devices are actually required by law to be reported by hospitals, including deaths and serious injuries related to the use of medical devices.

Reporting to FDA is mandatory for events where a medical device may have caused or may have contributed to a patient death or serious injury.

A "serious injury" means an injury or illness that:

- is life-threatening;
- results in permanent impairment of a body function or permanent damage to a body structure; or
- necessitates medical or surgical intervention to preclude permanent impairment.

A good tip to remember when it comes to mandatory reporting is, "you only need to suspect that a device was part of an event to report it and you don't have to know for sure." The suspicion that a device was involved is enough to trigger the requirement for a report

Unsure if you should report an event as mandatory or voluntary? Your FDA MedSun Analyst can help. Just call or email us!

[At-Home COVID-19 Antigen Tests-Take Steps to Reduce Your Risk of False Negative: FDA Safety Communication](#)

08/11/2022



FDA is advising people to perform repeat, or serial, testing following a negative result on any at-home COVID-19 antigen test, to reduce the risk an infection may be missed (false negative result) and to help prevent people from unknowingly spreading the SARS-CoV-2 virus to others. **The FDA recommends repeat testing following a negative result whether or not you have COVID-19 symptoms.** If you think you had a problem with your COVID-19 test, the FDA encourages you to send in a report through MedSun.

[Update: Certain Philips Respironics Ventilators, BiPAP Machines, and CPAP Machines Recalled Due to Potential Health Risks: FDA Safety Communication](#)

08/16/2022

UPDATE: On August 16, 2022, FDA updated this safety communication to provide the latest information about [Medical Device Reports](#) received from May 1, 2022 to July 31, 2022 that are associated with the breakdown of the polyester-based polyurethane foam used in the Philips Respironics Ventilators, BiPaP machines, and CPAP machines included in the June 2021 recall. In addition, FDA has taken additional actions since this updated communication was issued in November 2021. The updates are described in the [FAQs: What the FDA is Doing](#).

[FDA alerts patients, caregivers, and health care providers of cross-compatibility issues with autoinjector devices that are optional for use with glatiramer acetate injection](#)

08/18/2022

FDA is alerting patients, caregivers, and health care professionals that autoinjector devices that are optional for use with glatiramer acetate injection may not be compatible for use across FDA-approved glatiramer acetate injection drug products. FDA received reports that using an autoinjector that is not compatible with the patient's specific glatiramer acetate injection drug product has resulted in missed and partial doses. FDA requested that drug product manufacturers update their labeling to instruct users to confirm the autoinjector is compatible before using it to inject glatiramer acetate. FDA encourages health care professionals and patients to report adverse events or quality problems experienced using glatiramer acetate injection products to FDA MedSun.

[Safety Alert Regarding Use of Fecal Microbiota for Transplantation and Additional Safety Protections Pertaining to Monkeypox Virus](#)

08/22/2022

FDA is advising that clinical use of fecal microbiota for transplantation (FMT) has the potential to transmit monkeypox virus. Due to the potential for serious adverse events to occur, FDA has determined that additional protections are needed for any investigational use of FMT, whether used as part of a study under an Investigational New Drug Application (IND) on file with the FDA or otherwise, if it involves stool donated on or after March 15, 2022. Additional protections to implement now are listed [here](#). FDA is notifying Investigational New Drug Application (IND) holders of the potential risk of transmission of monkeypox virus via FMT and of FDA's determination that they need to develop and implement additional safety protections. FDA is communicating this information with this statement to all other stakeholders to ensure that everyone is fully informed. FDA will provide further information, as warranted, including on any additional protections pertaining to monkeypox that may be needed for use of FMT.

Certain Philips Respironics BiPAP Machines Recalled Due to a Plastic Issue: FDA Safety Communication

08/29/2022

FDA is alerting patients, caregivers, and health care providers that Philips Respironics (Philips) recalled certain bi-level positive airway pressure (also known as Bilevel PAP, BiPAP, or BPAP) machines that may contain a plastic contaminated with a non-compatible material. If that plastic is in the device motor, it may release certain chemicals of concern called volatile organic compounds (VOCs). The plastic may also cause the machine to fail and stop working suddenly during use. This recall is **not** associated with the PE-PUR foam issue impacting certain BiPAP machines recalled in June 2021. However, this new recall does apply to some of the devices recalled in June 2021.

Philips distributed [386 affected BiPAP machines](#) in the U.S. between August 6, 2020, and September 1, 2021.

If you treat a patient who has a health issue, including those listed [here](#) , or have any problem with your BiPAP device, we encourage you to report any problems with the device through FDA MedSun.



Funding opportunity announcement

Academic development of a training program for Good Laboratory Practices in high-containment environments

FDA [seeks to continue](#) a robust, collaborative, and educational program using problem-based learning techniques designed to bring researchers and regulators together to educate each other on the challenges related to these issues and to identify solutions that are acceptable from both scientific and regulatory perspectives. This program consists of the continued development and implementation of a certified, academic [training course](#) for instruction in Good Laboratory Practices (GLP) in a biosafety level (BSL) 4 high-containment environment. Applications are due by **11:59 p.m. ET, October 3, 2022**.

[Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices](#)

08/17/2022

Docket Number: [FDA-2017-D-6765](#)

This guidance is intended to update and provide clarity on the Replacement Reagent and Instrument Family Policy for manufacturers of IVD devices and FDA staff to promote consistent application of the concepts in this guidance. This guidance also incorporates concepts and recommendations from several of FDA's guidances and includes new recommendations and information in six areas. In addition, the guidance includes two appendices. [A copy of the document can be downloaded here.](#) [Read the Federal Register.](#)

[Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations - Premarket Notification \(510\(k\)\) Submissions](#)

08/17/2022

Docket Number: [FDA-2022-D-0986](#) (Submit comments by 10/17/2022)

This draft guidance to provide labeling recommendations for hydrogen peroxide-based contact lens care products (HPCPs) submitted in premarket notification (510(k)) submissions. These labeling recommendations are important because misuse associated with these devices has resulted in serious eye injuries. FDA believes that the labeling recommendations in this guidance may help manufacturers develop labeling with information about specific risks and directions for use of the HPCPs in conjunction with a user's prescribed contact lenses. These labeling recommendations are intended to promote the safe and effective use of HPCPs and ensure that consumers receive and understand information regarding the benefits and risks associated with the use of the device. [A copy of the document can be downloaded here.](#) [Read the Federal Register Notice.](#)

Free Education Modules to Share!

[Bench to Bedside: Integrating Sex and Gender to Improve Human Health](#) was developed in partnership between the FDA Office of Women's Health and the National Institutes of Health (NIH) to explore sex and gender related differences in key disease areas over 6 modules: Immunology, Cardiovascular Disease, Pulmonary Disease, Neurology, Endocrinology, and Mental Health. Through the joint providership of Johns Hopkins University School of Medicine and NIH, the Accreditation Council for Continuing Medical Education has designated these modules for a maximum of **six** American Medical Association Physician Recognition Award (AMA PRA) Category 1 Credit. Click [here](#) to review the modules, course authors, reviewers, leadership, and more information on claiming credit. Course expires 11/30/2023.

[Agreement for Shipment of Devices for Sterilization](#) — [21 CFR 801.150](#)

OMB Control Number 0910-0131—Extension

Docket Number: [FDA-2013-N-0375](#)

Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act ([21 U.S.C. 351\(c\)](#) and [352\(a\)](#)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations at § 801.150(e) ([21 CFR 801.150\(e\)](#)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms. The agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. In the **Federal Register** of March 15, 2022 ([87 FR 14540](#)), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Read the full document [here](#). If you would like more information on this item or to comment, click [here](#). Contact information: Amber Stanford, Office of Operations, FDA, 301-796-8867, PRASStaff@fda.hhs.gov.

[Medical Device Accessories](#)

OMB Control Number 0910-0823—Extension

Docket Number: [FDA-2016-N-1593](#)

FDA's guidance document entitled “Medical Device Accessories—Describing Accessories and Classification Pathways” is intended to provide guidance to industry and FDA staff about the regulation of accessories to medical devices, to describe FDA's policy concerning the classification of accessories, and to discuss the application of this policy to devices that are commonly used as accessories to other medical devices. In addition, the guidance explains what devices FDA generally considers an “accessory” and describes the processes under section 513(f)(6) of the Federal Food, Drug, and Cosmetic Act ([21 U.S.C. 360c\(f\)\(6\)](#)) to allow requests for risk- and regulatory control-based classification of accessories. In the **Federal Register** of March 16, 2022 ([87 FR 14891](#)), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Read the full document [here](#). If you would like more information on this item or to comment, please click [here](#). Contact information: Amber Stanford, Office of Operations, FDA, 301-796-8867, PRASStaff@fda.hhs.gov.

[Medical Device Labeling Regulations](#)

OMB Control Number 0910-0485—Revision

Docket Number: [FDA-2014-N-1048](#)

This information collection supports implementation of medical device labeling requirements governed by section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([21 U.S.C. 352](#)), codified in Agency regulations, and discussed in associated Agency guidance. In accordance with the Unique Device Identification (UDI) system (see part 801, subpart B ([21 CFR part 801, subpart B](#))), medical device labelers, unless excepted, are required to design and use medical device labels and device packages to bear a UDI, present dates on labels in a particular format, and submit data concerning each version or model of a device to the Global Unique Device Identification Database (GUDID) no later than the date the label of the device must bear a UDI. Once a device becomes subject to UDI requirements, respondents will be required to update the information reported whenever the information changes. FDA has identified requirements as having burdens that must be accounted for under the PRA; the burdens associated with these requirements are summarized in the posted document. [21 CFR 801.18](#) requires that whenever a labeler of a medical device includes an expiration date, a date of manufacture, or any other date intended to be brought to the attention of the user of the device, the labeler must present the date on the label in a format that meets the requirements of this section. The guidance document is intended to identify circumstances in which the name or symbol of the original SUD manufacturer is not prominent and conspicuous, as used in section 502(u) of the FD&C Act.

Read the full document [here](#). If you would like more information on this item or to comment, please click [here](#). Contact information: Amber Stanford, Office of Operations, FDA, 301-796-8867, PRASStaff@fda.hhs.gov.

Medical Devices; Humanitarian Use Devices—21 CFR part 814

OMB Control Number 0910-0332—Revision

Docket Number: [FDA-2017-N-4951](#)

This collection of information implements the humanitarian use devices (HUDs) provision of section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([21 U.S.C. 360j\(m\)](#)) and part 814, subpart H ([21 CFR part 814, subpart H](#)). Under section 520(m) of the FD&C Act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the FD&C Act ([21 U.S.C. 360d](#) and [360e](#)) provided that the device: (1) is designed to treat or diagnose a disease or condition that affects no more than 8,000 individuals in the United States; (2) would not be available to a person with a disease or condition unless an exemption is granted and there is no comparable device other than another HUD approved under this exemption that is available to treat or diagnose such disease or condition; and (3) will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. In the **Federal Register** of April 7, 2022 ([87 FR 20429](#)), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

Read the full document [here](#). If you would like more information on this item or to comment, please click [here](#).
Contact information: Amber Stanford, Office of Operations, FDA, 301-796-8867, PRAStaff@fda.hhs.gov.

Compounding Quality Center of Excellence Annual Conference Virtual

September 6, 2022 2:00 PM - 5:00 PM ET

September 7, 2022 11:00 AM - 4:30 PM ET

September 8, 2022 10:00 AM - 4:30 PM ET

The conference theme is “The Shared Pursuit of Compounding Excellence” and will highlight how stakeholders can protect patients from unsafe, ineffective, and poor-quality compounded drugs while preserving access to compounded drugs for patients who have a medical need for them. The conference will feature subject matter expert presentations, interactive sessions, and roundtable conversations. Attendees will be able to engage with FDA, learn about emerging trends, and gain quality compounding insights. Registration is free. Intended audiences include hospitals and healthcare professionals.

Click here for the [agenda](#). To [register for this event, click here](#).

2022 Scientific Computing Days Virtual

September 7, 2022 9:00am – 4:30pm ET

September 8, 2022 9:00am – 4:30pm ET

The 10th annual symposium is a conference promoting the latest advances in scientific computing technologies. This year’s theme is “Scientific Computing: In the Field, Around the World, and On the Edge.” The event’s goal is to help FDA improve the application of technology and scientific computing in support of FDA’s public health mission. Registration is free.

Click here for a [copy of event materials](#). To [register for this event, click here](#).

FDA Grand Rounds: Polio Vaccines: Past, Present and the Future Webcast

September 8, 2022 12:00 PM - 1:00 PM ET

FDA regulatory science played a leading role in the evaluation and the development of state-of-the-art quality control methods for the new generation of polio vaccines. The presentation will discuss the evolution of vaccines against poliomyelitis driven by the change in disease epidemiology, socio-economic circumstances, and advances in biotechnology. All participants **MUST register two days before the event** for webcast to view FDA Grand Rounds! The event is free. For technical help please contact: Madison.Hanson@fda.hhs.gov

Public Webinar - Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments – Draft Guidance Webcast

September 9, 2022 12:00 PM – 3:00 PM EDT

FDA is hosting this webinar to discuss and answer questions about the draft guidance: [Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments](#). Guidance 3 is the third in a series of four methodological patient-focused drug development (PFDD) guidance documents that describe how stakeholders (patients, caregivers, researchers, medical product developers, and others) can collect and submit patient experience data and other relevant information from patients and caregivers to be used for medical product development and regulatory decision-making. Guidance 3 discusses approaches to selecting, modifying, developing, and validating clinical outcome assessments to measure outcomes of importance to patients in clinical trials. This event is free.

[Register for this webinar here](#).

Real-World Data to Assess Variation in Opioid Prescribing and Use for Acute Pain in Diverse Populations Webcast

September 13, 2022 3:00 PM - 4:00 PM ET

Yale University – Mayo Clinic CERSI

Opioid analgesics are often used to treat moderate-to-severe acute non-cancer pain; however, there is little high-quality evidence to guide clinician prescribing. Many studies report the efficacy of opioids for acute pain, but few address the ideal dose and duration of treatment for various types of pain. The Acute Pain Pathways study was launched in collaboration with and supported by the FDA to understand the trajectories of pain and treatments experienced by a diverse group of opioid naïve patients who are prescribed an opioid analgesic for acute pain. In this talk, Dr. Jeffery will describe the study and present some preliminary results drawing from participants' reports of their pain severity and resolution, treatments used, satisfaction with care, and opioid handling and safety. This event will take place via a Zoom webinar livestream.

Login details will be shared upon [registration](#).

Contact information: LaToya Richardson at LaToya.Richardson@fda.hhs.gov.

Advancing Pre-Market Safety Analytics Virtual

September 14, 2022 12:00 PM - 5:00 PM ET

FDA and the Duke-Margolis Center for Health Policy will host a one-day virtual meeting focused on advancing pre-market safety analytics.

Due to lack of standardization of safety data analysis and visualization, inconsistencies exist in how adverse events are defined, categorized, analyzed, and presented in marketing applications. FDA led the development of two documents to facilitate review of safety data:

1. A standardized approach in grouping preferred terms known as the FDA Medical Queries (FMQ).
2. Standardized methods for visualization of safety data into tables and figures known as the Standard Safety Tables and Figures Integrated Guide (STF-IG).

This virtual workshop is open to the public with no cost to attend, but [registration is required](#).

You will find the [draft agenda here](#).

Contact information: Christopher Smith, Office of Drug Evaluation Science, Center for Drug Evaluation and Research, FDA at ONDbiomedicalinformatics@fda.hhs.gov.

An Overview of Sentinel's Publicly Available Analytics Tools webinar

September 14, 2022 12:00PM – 1:00 PM ET

This webinar will explore the resources available in [Sentinel](#) for individuals unfamiliar with Sentinel's analytics tools and the Sentinel Common Data Model. Please register in advance.

FDA Workshop: Increasing the Efficiency of Biosimilar Development Programs Virtual

September 19, 2022 9:00 AM - 4:00 PM ET

The workshop will focus on comparative clinical studies associated with biosimilar development programs and will discuss possible innovative ideas that have the potential to streamline and improve the efficiency of biosimilar development. See website for agenda. The workshop will include presentations and panel discussions by FDA staff as well as external subject matter experts in biostatistics. The workshop is free and [registration is required](#).

Contact information: Office of Therapeutic Biologics and Biosimilars, Office of New Drugs, Center for Drug Evaluation and Research, CDER-BiologicsBiosimilarsInquiries@fda.hhs.gov.

Advancing Generic Drug Development: Translating Science to Approval Workshop

September 20, 2022 8:00am – 5:10pm ET

September 21, 2022 8:am – 5:00pm ET



This virtual public workshop will communicate how outcomes from FDA research conducted under the Generic Drug User Fee Amendments (GDUFA) guide and facilitate generic drug development, regulatory assessment, and approval. This workshop will focus on common issues seen in abbreviated new drug applications (ANDAs), link GDUFA science and research on complex products and scientific issues to product-specific guidance development, and pre-ANDA meeting discussions, and examine various areas of innovative science and cutting-edge methodologies behind generic drug development. This workshop will also provide some insight into upcoming GDUFA III enhancements. Topics covered include drug-device combination products. Real-time attendance is required for the certificate of attendance which can be used in support of CEs from sponsoring professional organizations.

KEYNOTE SPEAKER Robert M. Califf M.D., MACC, Commissioner of Food and Drugs

The workshop is free and registration is required. An agenda is available here.

Contact information: Please contact info@sbiaevents.com for all technical questions.

Vaccines and Related Biological Products Advisory Committee September 22, 2022 Meeting Announcement ADVISORY COMMITTEE MEETING*

September 22, 2022 8:30 AM - 5:00 PM ET

Docket Number: [FDA-2022-N-1608](#) (closes on September 21, 2022)

**Please note: Due to the impact of the COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform.*

The committee will meet in open session to discuss the Biologics License Application # 125739 (BLA - 125739) from Rebiotix Inc. for a product, Rebyota (Fecal Microbiota, Live), with a requested indication to “reduce the recurrence of Clostridioides difficile infection (CDI) in adults following antibiotic treatment for recurrent CDI.”

For more [information regarding the meeting, participation, and how to comment, please click here](#).

Contact information:

- Sussan Paydar or Prabhakara Atreya, 240-506-4946, CBERVRBPAC@fda.hhs.gov
- FDA Advisory Committee Info Line: 1-800-741-8138
- Please call the Information Line for up-to-date information on this meeting

September 22-23, 2022: Meeting of the Oncologic Drugs Advisory Committee Meeting Announcement ADVISORY COMMITTEE MEETING*

September 22, 2022 9:00 a.m.to 6:00 p.m. ET

September 23, 2022 9:00 a.m. to 1:15 p.m. ET

Docket number: [FDA-2022-N-0634](#) (closes on September 21, 2022)

**Please note: Due to the impact of the COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform.*

During the first session of September 22, 2022, the committee will discuss new drug application (NDA) 215643, for poziotinib tablets, submitted by Spectrum Pharmaceuticals, Inc. The proposed indication (use) for this product is for the treatment of patients with previously treated, locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring HER2 exon 20 insertion mutations. Select patients with NSCLC for treatment with poziotinib based on the presence of HER2 exon 20 insertion mutations using an FDA-approved test.

During the second session of September 22, 2022, the committee will hear an update on new drug application (NDA) 214383, for PEPAXTO (melphalan flufenamide) for injection, submitted by Oncopeptides A.B.

COPIKTRA (duvelisib) capsule, submitted by Secura Bio, Inc.

For more [information regarding the meeting, participation, and how to comment, please click here](#).

Contact information:

- She-Chia Chen, Center for Drug Evaluation and Research, FDA 240-402-5343, ODAC@fda.hhs.gov
- FDA Advisory Committee Information Line, 1-800-741-8138
- Please call the Information Line (1-800-741-8138) for up-to-date information on this meeting.

[FDA AAPS EUFEPS 5th Annual GBHI Meeting](#) Public

September 28, 2022 8:00 AM - 10:30 PM ET

September 29, 2022 9:00 AM - 5:30 PM ET

The Global Bioequivalence Harmonization Initiative (GBHI) workshop provides an open forum for pharmaceutical scientists from academia, industry and regulatory agencies to discuss various bioequivalence topics at issue. The main goal is to update participants on the national and international initiatives affecting the development of safe and effective pharmaceutical drug products via global bioequivalence harmonization initiatives.

Contact information:

- Padmaja Mummaneni, Ph.D., 301-796-2027; padmaja.mummaneni@fda.hhs.gov
- Mehul Mehta, Ph.D., 301-796-1573; mehul.mehta@fda.hhs.gov

[Vaccines and Related Biological Products Advisory Committee October 6, 2022 Meeting Announcement](#) Advisory Committee Meeting*

October 6, 2022 8:30 AM - 12:40 PM ET

**Please note: Due to the impact of the COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform.*

Docket Number: [FDA-2022-N-1745](#) (closes October 5, 2022)

The committee will meet in open session to discuss strain selection for influenza virus vaccines for the 2023 Southern Hemisphere influenza season. FDA intends to make background material available to the public no later than 2 business days before the meeting. Materials for this meeting will be available at the [meetings main page](#).

Contact information:

- Sussan Paydar or Prabhakara Atreya, CBER, FDA, 240-506-4946, CBERVBPAC@fda.hhs.gov
- FDA Advisory Committee Information Line, 1-800-741-8138

[Co-sponsored Public Workshop - Expediting Innovation of Bioelectronic Implants for Vision Restoration](#) Workshop

October 24, 2022 8:30am – 4:30pm ET

October 25, 2022 8:30am – 4:30pm ET

FDA is co-sponsoring a workshop with the University of Pittsburgh. The purpose is to provide a forum for all stakeholders to share their perspectives on the safety and effectiveness of bioelectronic implants for vision restoration.

This workshop aims to foster a conversation about vision challenges and include discussions regarding the relevant regulatory pathways for these types of implants, nonclinical data requirements, possible novel safety and effectiveness clinical endpoints, aspects of technology translation, possible methods to conduct real-life daily activities assessments for low vision patients, and possible methods to collect patient reported outcome measures related to bioelectronic implants for vision restoration. The workshop also includes discussions related to patient perspectives and experiences with bioelectronic implants, and some of the elements that are important to patients when considering the benefits and risks of using these devices. [Registration required.](#)

Contact information: Michelle Gabriele Sandrian, CDRH, 301-796-6620, CDRH-VisionWorkshop@fda.hhs.gov

Bridging Efficacy and Safety to the Obese: Considerations and Scientific Approaches Virtual

November 9, 2022 8:30 AM - 4:15 PM ET

FDA in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI) will host this one-day virtual public workshop. The purpose of this workshop is to review the implications of obesity in adult and pediatric patients on safety, efficacy, drug dosing and disposition.

Besides the major health and socioeconomic implications of obesity, there are great challenges in ensuring the optimal use and development of drugs for the growing population of obese persons. Obese patients are a large segment of the U.S. population and should be included in drug development studies. There are presently no clear dosing guidelines for obese pediatric patients. Although smaller clinical studies have begun to examine drug pharmacokinetics in obese pediatric patients, the relationship between pediatric obesity and drug response, including efficacy and safety, has not been thoroughly elucidated. Advancing this field requires identifying key knowledge gaps and barriers to the conduct of such studies and potential innovative solutions to improve data generation and analysis.

The workshop is free and [registration is required](#).

For [more information and to view the draft agenda, click here](#).

Contact information: Althea Cuff, Office of Clinical Pharmacology, CDER, FDA, OCPWorkshops@fda.hhs.gov



[Click here to find more upcoming FDA Meetings, Conferences and Workshops!](#)



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Excellent customer service is important to us. [Thank you for providing feedback about the service you received](#). It should take less than three minutes to complete the survey. Your response is anonymous and will be used to improve CDRH Customer Service.

Your participation/nonparticipation is completely voluntary, and your responses will not influence your eligibility in receiving any FDA services.

OMB Control No. 0910-0360, expires 10/31/2023

The Center for Devices and Radiological Health (CDRH) offers an innovative learning opportunity for CDRH. [The Experiential Learning Program \(ELP\)](#) is a collaborative approach to closing the knowledge gap between emerging and innovative technology and the pre-market review of medical devices. It is essential that CDRH staff are aware of and understand how medical devices are used in the clinical setting.

The ELP is intended to support CDRH staff with an opportunity to understand the Total Product Life Cycle. CDRH is committed to understanding current innovative technologies, regulatory impacts and needs, and how patient perspective and quality systems management advances the development and evaluation of innovative devices and monitor the performance of marketed devices.

Learning from our Partners

These formal training visits are not intended for the FDA to inspect, assess, judge, or perform a regulatory function, but rather, they are an opportunity to provide CDRH review staff with a better understanding of the products we review, the voice of the patient, challenges related to management in the product life cycle, and how medical devices fit into the larger healthcare system. CDRH encourages participation from a variety of providers and groups including academia, and clinical facilities, and others. If you have questions, please reach out to us at [ELP Inquiries](#) or (240) 402-2246.

Training Areas of Interest

The ELP provides groups of CDRH staff with opportunities to observe operations in a variety of areas. The Training Areas of Interest reflect topics identified by CDRH managers and are listed below. If you are interested in ELP participation, please review the table located below.

Virtual Site Visits

The ELP now offers virtual site visits, which allows greater flexibility in selecting staff and proposals as well as increasing exposure to the program. You can indicate if you wish to host a virtual ELP site visit on your application.

Patient Engagement

Patient engagement is defined as intentional, meaningful interactions with patients that provide opportunities for mutual learning and effective collaborations. CDRH is responsible for helping to ensure the safety and effectiveness of medical devices marketed in the United States as well as assuring that patients and providers have timely and continued access to high-quality, safe, and effective medical devices and as such continues to include patient engagement in its [2022-2025 Strategic Priorities](#).

Gaining the perspective of our stakeholders and understanding implementation of how these principles are applied within their institutions will provide great insight to the FDA's staff. CDRH is interested in learning how others incorporate patient input into a phase or phases of a device's life cycle. Please consider including Patient Engagement as a supplement topic to your ELP Site Visit Request submission.

NEW: CDRH is soliciting proposals for site visits that can be accommodated on-site or virtually. In addition, CDRH encourages the submission of proposals addressing Patient Engagement as a supplemental topic.

The 2023 Fall ELP Proposal Submission Period is *OPEN now until September 6, 2022, at 12pm EST.*

Application Process

If your facility is interested in submitting a proposal, please first confirm the Submission Period is open and that your proposal supports the current CDRH training topics of interest.

Details for the Application Process can be found on the [CDRH Experiential Learning Program Website](#). All proposals must be submitted by email to [ELP Proposal Submissions](#). For questions about the ELP Program, please contact [ELP Inquiries](#) or (240) 402-2246.

Related Resources

- [Sample Site Visit Request](#)
- [Example of Site Visit Agenda](#)
- [Site Visit Do's and Don'ts](#)
- [CDRH's Experiential Learning Program website](#)
- [2023 Fall Areas of Interest](#)

The following table contains the Fall Fiscal Year 2023 Experiential Learning Program (ELP) Areas of Interest.

Digital Health/Software		
Areas of Interest	Anticipated Participants	Identifier
Novel Digital Health Technologies and Therapy – Innovations in digital health technologies and therapies have accelerated medical device advancements. Technologies such as mobile platforms, wearables, virtual and augmented realities (VR/AR), and other computing platforms have increasingly been adapted to deliver healthcare to patients. Many of these applications are novel and present new opportunities for patients and health care providers to measure, treat, diagnosis, and/or manage diseases and conditions. Furthermore, advanced algorithms (such as artificial intelligence, machine learning), have enhanced the capabilities of digital health technologies and provide for new opportunities to improve performance from real-world use and experience. The novelty of these innovative digital health technologies and therapies often raise new questions of safety and effectiveness. Therefore, it is important to fully understand these products, as described by the software development and deployment processes, clinical validation, risk and cybersecurity management, lifecycle requirements, and other activities that demonstrate responsible and high-quality digital health innovation.	Cross Cutting	2023 B1
Real World Data & Evidence (RWD & RWE) – The FDA currently defines real-world data (RWD) as the data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources, such as electronic health records, registries, medical claims, and data from wearables and other digital health technologies. Improvements in interoperability and increasing availability of computers, cloud computing, mobile devices, wearables, and other digital health technologies to measure, collect, and/or store large amounts of health-related data has been accelerating the opportunities leverage RWD/RWE throughout health care. Additionally, innovations in medical devices, including mobile apps, have also resulted in novel data sources, including the device itself. Through advancements in RWD and analysis methods (for example, artificial	Cross Cutting	2023 B2

intelligence, machine learning), there is growing potential to generate robust real-world evidence (RWE) to further support FDA regulatory decisions. It is important for FDA to understand, foster, and harness the increasing power of RWD/RWE to accelerate medical product development and bring new innovations faster and more efficiently to the patients who need them, without compromising patient safety. Furthermore, it is important to understand and advance the potential use RWD/RWE to support solutions that address health disparities and promote health equity.		
OCEA - Office of Clinical Evidence Analysis		
Areas of Interest	Anticipated Participants	Identifier
Leveraging data from real-world experience is critical to bringing medical diagnostics and therapeutics to US patients first in the world. Evaluating the strengths and limitations of those data depends on understanding how the data move through the eco-system from the point of care to a reviewer's desk. This includes understanding of how clinical data are entered into various systems (such as electronic health records, claims, and registries) as part of the clinical workflow and for what purposes, which can shed light into the quality of the data submitted. This also includes understanding considerations for who can access those data and for what purposes, which provides context for whether certain data can be used, and how quality might be impacted by any processing of the data that might need to occur as a result of data ownership considerations. This also involves understanding of the entities involved in transforming the data (such as data visualization, governance, aggregation, linkage, analytics, and curation,) to understand where quality of those data might be impacted.	Cross Cutting	2023 P1
OHT 2 – Cardiovascular Devices		
Areas of Interest	Anticipated Participants	Identifier
Non-Clinical Cardiovascular Medical Device Testing – This training will provide hands-on/in-person experience on the following topics to augment staff's knowledge on various ISO testing, development of silicone models for in vitro analyses, in-person knowledge on common testing equipment used for cardiac and cardiovascular device testing systems, and development/implementation of simulated use systems. The experience will also include knowledge on how standard test methods may be adapted and developed to address testing needs for device specific applications, which is common practice to address regulatory submission requirements.	OHT 2	2023 E1
OHT 3 - Reproductive, Gastro-Renal, Urological, General Hospital Device & Human Factors		
Areas of Interest	Anticipated Participants	Identifier
Reprocessing and Sterilization – Flexible Endoscopes – The FDA continues to work to improve the effectiveness of reprocessing of various scopes, including duodenoscopes. Reprocessing of scopes used in medical procedures, from the initial cleaning stage through final reprocessing, is vital toward reducing the risk of infection for patients. Scope reprocessing includes several products and processes, for example automated rinsing devices, disinfectants, and drying and storage practices. The FDA would like to visit a reprocessing facility to improve our holistic understanding of scope reprocessing and how each aspect impacts the safety of these reusable devices.	OHT 3	2023 F1

Implantable Neurostimulation Devices – Manufacturing and Post-market Surveillance – The FDA reviews neurostimulation devices for urinary and fecal incontinence, deep brain stimulation, spinal cord stimulation, and other applications. These are complex systems with many components and with evolving technologies. The FDA would like to learn more about the manufacturing and postmarket surveillance for these high-risk class III devices.	OHT 3	2023 F2
OHT 5 - Neurological & Physical Medicine Devices		
Areas of Interest	Anticipated Participants	Identifier
Neurological Stereotactic Navigation Systems – Clinical observation of stereotactic neurosurgery procedures and research and development of neurological stereotactic systems.	OHT5	2023 H1
Prosthetics/Neuromodulation Medical Devices – Prosthetics development is a rapidly advancing area that can potentially serve both civilian and military service personnel patient populations where amputee and spinal cord injury represents broad US public health challenges. Neurostimulation devices have the potential for substantial public health impact on mental or physical impairments because of the high incidence in psychiatric and neurological conditions. Several types of marketing submissions in the prosthetic and neuromodulation sector include pre-submissions, 510K, de novo, and Premarket Approval (PMA) regulatory paths. Moreover, several potential Sponsors may have competitive submissions for this call for ELP proposals. In addition, other Offices may have staff interested in these topics areas with related technologies in the orthopedics and cardiovascular technology sectors.	OHT5	2023 H2
OHT 6 - Orthopedic Devices		
Areas of Interest	Anticipated Participants	Identifier
Patient matched implants and cutting guides (Imaging Modality, Segmentation, Device Design, Final Device) – Personalized medicine is being explored throughout the medical device ecosystem and is no stranger to use in Orthopedic devices (patient matched devices have been authorized for use in both implants and instruments). The patient matched device design process can require heightened interactions with the clinical care team, and on the manufacturer's, end requires specialized expertise to ensure imaging scan segmentation is performed correctly and that the device design will fit the patient's anatomy and patients need. Moreover, there can be much variability in this process due to the differences in imaging modality, technology utilized by manufacturers and their specific clinical expertise and training/standard operating procedures. The FDA is interested in learning about the types of software used and how they are applied to the process. The FDA is also interested in learning the specifics of the patient matched process, including who needs to perform each step of the process, how the engineer is trained, what the necessary expertise are for each program type/approach, how patient matching process is best employed and monitored, when patient matched devices are more valuable to employ compared to off the shelf solutions, what the limitations are for matching a device to fit both the patients surrounding bony anatomy or a patient's pre-existing implants (for example, device intended to mate with existing ankle replacements). Some examples of this process include patient matched arthroplasty replacements, patient matched cutting guides and additively manufactured custom devices.	Cross Cutting	2023 I1
OHT 7 - In Vitro Diagnostics		

Areas of Interest	Anticipated Participants	Identifier
<p>Clinical Laboratory Tour –</p> <p>A. Clinical laboratory workflow, patient sample testing workflow, clinical lab analyzers and instrumentation –</p> <p>B. Next generation sequencing laboratory workflow, preanalytical and analytical processing, sequencers, bioinformatic processing, clinical interpretation</p>	OHT7	2023 J2
OHT 8 - Radiological Health		
Areas of Interest	Anticipated Participants	Identifier
<p>Radiology Image Reading –</p> <p>Radiology workflow involves radiologists analyzing images to help diagnose a patient. This often involves reviewing many images from patients with varying diseases. Software devices can aid in the radiology workflow by helping to automatically locate, identify, or triage images. Therefore, there is interest in academic or hospital-related sites that target diagnostic devices for patient management to facilitate our understanding of patient workflows and the roles the radiologic imaging devices (hardware and software) and, where possible, in the diagnostic setting or in actual clinical use. Preferred sites would be clinical sites with live cases included (for example, cath lab, interventional radiology suite), and/or the live use of Computer Aided-Diagnostic (CAD) software in the interpretation workflow, and educational instructional sessions, to understand the workflow from diagnosis to patient treatment.</p>	OHT8	2023 K2
ORP – Office of Regulatory Programs		
Areas of Interest	Anticipated Participants	Identifier
<p>Evaluating sources of data for adverse event and signal identification –</p> <p>Medical Device associated events, their evaluation, escalation, investigation and actions a manufacturer may take to improve performance. Including in this focus is their connection with other data sources (internal and external), utilization of AI and other signal detection logics.</p>	Cross Cutting	2023 L2
OSEL - Office of Scientific Engineering Labs		
Areas of Interest	Anticipated Participants	Identifier
<p>3D Printing in a Healthcare Setting –</p> <p>The Center for Devices and Radiological Health (CDRH) is committed to assuring that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. As part of providing this assurance, CDRH recognizes that innovations in manufacturing and product delivery are as important as innovations in device design and functions. 3D printing in a healthcare setting may serve an important public health purpose and may provide for rapid and agile production of devices, including but not limited to patient-matched devices² and anatomical models for surgical planning. This technology has the potential to help a healthcare facility (HCF) quickly respond to patient needs, bring personalized care to patients in a timely manner, and lead to new innovations in patient care and treatment. Areas of interest include healthcare settings engaged in 3D printing to support patient care, especially those working under a quality management system.</p>	Cross Cutting	2023 M1

Patient Engagement

Areas of Interest	Anticipated Participants	Identifier
<p>Patient Engagement during all phases of medical device total product life cycle –</p> <p>Patient engagement is defined as intentional, meaningful interactions with patients that provide opportunities for mutual learning and effective collaborations. The FDA/CDRH is interested in learning how medical device innovators, developers, manufacturers, distributors, investigators, and others incorporate patient input into a phase or phases of a device’s life cycle. These phases may include discovery and ideation, invention and prototyping, pre-clinical testing, pre-market clinical testing (for example, trial design and conduct), product launch, and post-market activities (such as post-market study design, labeling, and recalls).</p>	Cross Cutting	2023 Q1
Reprocessing and Sterilization		
Areas of Interest	Anticipated Participants	Identifier
<p>Reprocessing, Disinfection, and Sterilization –</p> <p>The FDA takes the risk of patient infection very seriously and continually works to take steps to help improve the effectiveness of reprocessing, disinfection, and sterilization of various medical devices. Reprocessing of reusable medical devices includes the initial cleaning stage through final reprocessing through disinfection or sterilization, depending on the overall risk of contamination of the device. Interest is centered around types of cleaning agents/disinfectants and their effectiveness, material compatibility, overall effectiveness of reprocessing including adequate log reduction of bioburden (disinfection), support of achieving an appropriate Sterility Assurance Level (sterilization) and drying of the medical devices after cleaning and reprocessing through validation of reprocessing instructions proposed by the sponsor. In addition to validating the cleaning and reprocessing of the device, monitoring the reprocessing procedures to include sampling and culturing would be beneficial in understanding the reduction in risk of infection.</p>	Cross Cutting	2023 N1
ELP Participation Structure Key		
<p>Combination Products</p> <p>Digital Health</p> <p>OHT 2 – Cardiovascular Devices</p> <p>OHT 3 – Reproductive, Gastro-Renal, Urological, General Hospital Device & Human Factors</p> <p>OHT 5 – Neurological & Physical Medicine Devices</p> <p>OHT 6 – Orthopedic Devices</p> <p>OHT 7 – In Vitro Diagnostics</p> <p>OHT 8 - Radiological Health</p> <p>OCEA – Office of Clinical Evidence and Analysis</p> <p>ORP – Office of Regulatory Programs</p> <p>OSEL - Office of Scientific Engineering Labs</p> <p>Patient Engagement</p> <p>Reprocessing</p> <p>Cross Cutting – Potentially including multiple offices within CDRH</p>		





The reports that follow represent a cross section of device related events sent by MedSun Reporters during the prior month. The reports are presented as submitted by MedSun Representatives and in some instances, have been summarized and/or edited for clarity. The MedSun report database is [here](#).



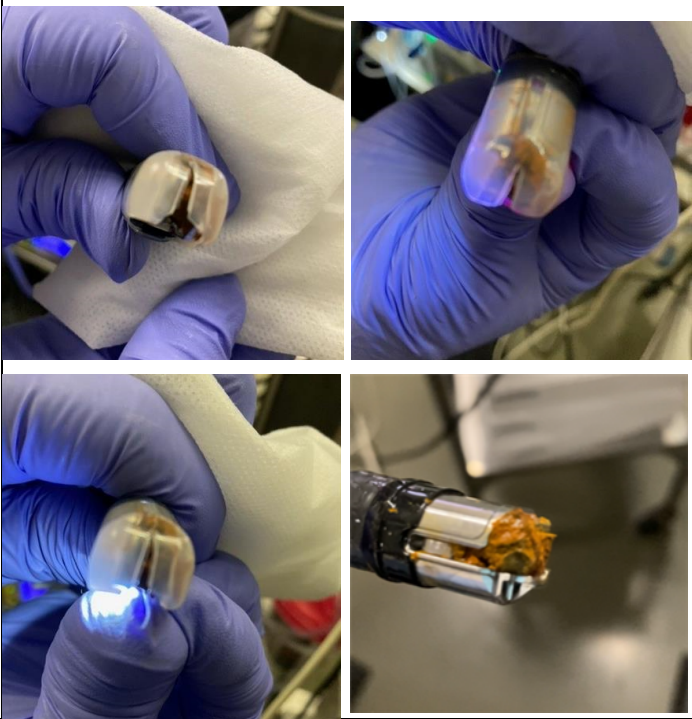
The lollipop icon distinguishes highlighted reports that describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations. FDA defines pediatric patients as those who are 21 years 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
Type: Needle, Hypodermic, Single Lumen <u>Brand:</u> BD Eclipse <u>Model #:</u> 305759 <u>Lot #:</u> 1175667 <u>Cat #:</u> 305759	BECTON, DICKINSON AND COMPANY	The BD Eclipse Needle packaging and needle hub color is identical for both the 25g 1 1/2" and the 25g 5/8" needles. The hub is orange and the needle cover is light lavender. On the Labor Delivery unit, the inappropriate large needle size was stocked, and no one realized it until the cap was removed. It was considered a safety concern if it was used on a newborn. It is requested that the manufacturer consider changing this color confusion. There was no harm to anyone because the needle was not used, and the supplies were removed from the unit to prevent any potential error from occurring.
Type: Set, Administration, Intravascular <u>Lot #:</u> 5877677 <u>Cat #:</u> CH2000S-C	ICU MEDICAL, INC.	Patient called Registered Nurse (RN) in during Etoposide flush (approx. 5 minutes left). Line had come unattached and was backflowing blood onto the sheets. RN stopped the infusion, cleaned up bedding and Hep-locked patient. Upon further inspection of line, RN noticed that the Spiros that was attached to the filter and the Trifuse had broken off. The connection point would reconnect and spin as if the line had been "cracked" and wouldn't come undone, but it could be pulled off if enough pressure was used pulling backwards. RN used 1-2 wipes, changed patient sheets, replaced chemo tubing, and saved the line in a biohazard bag.
Type: Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days <u>Brand:</u> PowerPICC Provena <u>Model #:</u> S1275108FD5	Bard Access Systems, Inc.	The 5 French double lumen PICC unable to trace ECG as the wire was not picking up tracing.


Device	Manufacturer	Problem
<u>Lot #:</u> regn3999 <u>Cat #:</u> S1275108FD5		
Type: Thermometer, Electronic, Clinical  <u>Brand:</u> Novaplus Digital Thermometer, Pediatric, Duck Cap <u>Lot #:</u> 20210108 <u>Cat #:</u> VDTs-100D <u>GUDID#:</u> (1)00856899 004113 (10) 20210108	ELKA Corporation	<p>When RN removed thermometer from package, duck head came off. This is a safety issue as a child could choke on the head. In addition, there is a button battery right under the duck head. Button batteries can cause serious injury or death if swallowed.</p> <p>Nursing Staff suggest manufacturer make the device with a single battery without pop off top.</p> <p>=====</p> <p>Manufacturer response for Pediatric Flexible Tip Digital Thermometer, Novaplus Digital Stick Thermometer (per site reporter)</p> <p>=====</p> <p>I received an email from manufacturer's official person in addition to a phone call from a ELKA Representative Quality Team. Device is available for return to the manufacturer for investigation. Awaiting response and mailing labels to process return of product.</p>
Type: Set, Administration, Intravascular <u>Brand:</u> Clearlink/Continu-Flo/Duo-Vent <u>Model #:</u> 2C8541 <u>Lot #:</u> (10)R22C14017 <u>Cat #:</u> 2C8541	BAXTER INTERNATIONAL INC.	<p>Registered nurse (RN) notified that patient's Pertuzumab had leaked onto the patient's shirt from the y-site of the tubing. Infusion stopped. Faulty tubing and remainder of medication placed in chemo bag and returned to pharmacy. Primary RN notified Team. Patient assisted in cleaning skin and removing clothes. Patient given gown to wear. RN replaced primary line. RN noted that saline was leaking out of y-site of primary line of tubing. RN tried another primary line of tubing from the same lot and had the same thing happen. Tubing type: Continu-Flo Solution, with DUO-Vent Spike. Lot: (10)R22C14017.</p> <p>=====</p> <p>Manufacturer response for infusion pump tubing, IV pump Set Continu-Flo 10 drops/mL drip rate 105 inch tubing 3 ports (per site reporter)</p> <p>=====</p> <p>The manufacturer has acknowledged receipt of the product complaint, still awaiting an official response.</p>
Type: Set, Administration, Intravascular <u>Brand:</u> Clearlink/Continu-Flo/Duo-Vent <u>Lot #:</u> (not provided) <u>Cat #:</u> 2C8541	BAXTER INTERNATIONAL INC.	<p>A chemotherapy spill occurred from a port on the side of our Baxter tubing set. Neither Nursing nor the pharmacy staff manipulated this port during compounding, dispensing, or administration. Health care provider have communicated previous similar issues with the product manufacturer and were offered no implementable solutions to prevent a recurrence.</p> <p>Health care providers captured the product number, lot number, and expiration date in our computer system but, unfortunately, health care providers remain unable to access the information due to an EHR glitch. Health care providers were told this will be resolved so hopefully they</p>

Device	Manufacturer	Problem
		<p>can provide information later this week. Without being able to confirm, health care provider expects the tubing set used was 2C8541. Again, they'll confirm later this week.</p> <p>=====</p> <p>Manufacturer response for Tubing set of infusion pump, IV Pump Set Continu-Flo 10 drops /mL drip rate 105 each tubing 3 ports (per site reporter)</p> <p>=====</p> <p>Apology from the manufacturer, described by the manufacturer as not a widespread issue with their product but rather isolated events to our hospital. Although this may be the first incident reported to MedSun, we have tracked an estimated 8 similar incidents of tubing leaks this rolling calendar year.</p>
<p>Type: Oximeter</p> <p><u>Brand:</u> Nellcor Flexible SpO2 Reusable sensor, Flexmax-P</p> <p><u>Model #:</u> FLEXMAX-P</p> <p><u>Cat #:</u> FLEXMAX-P</p> <p><u>Other</u></p> <p><u>#:</u> 10884521532311</p>	Covidien LP	<p>Pulse oximetry sensors are weight based for most accurate/reliable results. The package for the Flexmax-P states for use >20kg, the Nellcor Pulse Oximetry Sensors Quick Reference Guide states for use <20kg. This is a huge difference in patient population for use and has the potential to have inaccurate SpO2 measurements. (Page 5 of Nellcor brochure)</p> <p>We have never used this product on a patient - just obtaining for use.</p> <p>Link to full brochure: https://www.medtronic.com/content/dam/covidien/library/us/en/product/pulse-oximetry/nellcor-sensor-quick-reference-brochure.pdf </p> 
<p>Type: Oximeter</p> <p><u>Brand:</u> O3</p> <p><u>Model #:</u> 4235</p> <p><u>Cat #:</u> 4235</p>	MASIMO CORPORATION	<p>A patient had placement of NIRS (Near-Infrared Spectroscopy) monitor on the lower left flank. The patient developed an unstageable pressure injury at the location of the probe.</p>

Device	Manufacturer	Problem
<p><u>Type:</u> Oximeter</p> <p><u>Brand:</u> O3</p> <p><u>Model #:</u> 4235</p> <p><u>Cat #:</u> 4235</p>	MASIMO CORPORATION	Patient had placement of NIRS (Near-infrared spectroscopy) monitors on right and left flanks and developed pressure injuries at both sites.
<p><u>Type:</u> Endoscope, Accessories, Narrow Band Spectrum</p> <p><u>Brand:</u> Single Use Distal Cover</p> <p><u>Model #:</u> MAJ-2315</p> <p><u>Cat #:</u> MAJ-2315</p> <p><u>Other #:</u> GUDID 14953170403016</p> <p>There weren't any procedural or anatomical difficulties that were known to have contributed to the distal cover splitting. Once the duodenoscope was cleaned, the scope was found to be in working order and the elevator was moving without issue and therefore it was not returned to Olympus.</p>	OLYMPUS MEDICAL SYSTEMS CORP.	<p>Patient underwent ERCP using a new disposable cover duodenoscope. During the procedure while using the balloon, the balloon popped. This was an unusual occurrence. A second balloon was inserted and it was noticed that it was stretching and not performing properly. It was removed just before it also popped. A stent was then passed through the scope and then it was noticed that the elevator was very resistant but the stent was able to be successfully deployed. Upon removing the duodenoscope from the patient, it was immediately noticed that the disposable duodenoscope cover was split in half. Behind the cover was several stone-like material lodged in the distal tip. This was thought to be the likely reason the elevator channel was so resistant. Of note, under normal circumstances, the duodenoscope cover remains intact and at the end of the case, it is required to crack the cover to get it off the scope, so splitting of the cover is expected but it should not occur while in the patient.</p> <p>There weren't any procedural or anatomical difficulties that were known to have contributed to the distal cover splitting. Once the duodenoscope was cleaned, the scope was found to be in working order and the elevator was moving without issue and therefore it was not returned to Olympus.</p> <p>The procedure was completed without any adverse effects to the patient as a result of the difficulties experienced during the procedure. The patient was discharged home in stable condition.</p> <p>After this event with the duodenoscope, the physician requested that we bring back our old duodenoscopes.</p> <p>=====</p> <p>Manufacturer response for Endoscope, accessories, narrow band spectrum, SINGLE USE DISTAL COVER (per site reporter)</p> <p>=====</p> <p>The Olympus rep provided a duodenoscope cover application in-service to the GI technicians.</p>

Device	Manufacturer	Problem
		
<p><u>Type:</u> Endoscopic Grasping/cutting Instrument, Non-powered</p> <p><u>Brand:</u> Diagnostic FTRD Set</p> <p><u>Model #:</u> 13</p> <p><u>Lot #:</u> 826006</p> <p><u>Cat #:</u> 200.76</p>	<p>Ovesco Endoscopy AG</p>	<p>The colonoscopy was completed and polyp at appendiceal orifice was noted. The scope was withdrawn and the team set up for FTRD (full thickness resection device) with OTSC (over the scope clip). Once set up, the scope was deployed, the area for resection was marked and the FTRD grasper was deployed. The tissue was grasped and pulled into the cap of the FTRD. The physician stated that once the tissue was pulled in, she deployed the clip and the snare. She stated she could not see much due to tissue obstructing her view. Once the clip was thought to be deployed and the hot snare activated with tissue cut, scope was withdrawn and the tip is noted to have blood on it with the clip still attached, the scope was re-inserted and the site of the FTRD inspected and found to be bleeding. Nine (9) Endo clips were deployed and the bleeding appeared to be controlled. The Ovesco clip did not deploy after turning the mechanism that is designed to deploy the clip. The intra-procedure team thought the clip had been deployed and the tissue that was involved was hot snared. After snaring, the Ovesco clip was visualized by the team still on the deployment device. The patient required surgery to repair the cecal perforation at the base of the appendix. This required a lengthened hospital stay. The device and packaging were not saved, therefore unable to determine whether this was user-error, device malfunction, or anatomy related.</p>

Device	Manufacturer	Problem
<p>Type: Container, I.V.</p>  <p><u>Brand:</u> EcoFLX Empty Mixing Container</p> <p><u>Model #:</u> DMP0150 <u>Lot #:</u> B21-5536 <u>Cat #:</u> DMP0150</p>	<p>DOUGLAS MEDICAL PRODUCTS, INC.</p>	<p>Douglas Medical Product EcoFLX empty mixing containers have had multiple malfunctions of leaking partially or entirely, both in patient rooms and in medication rooms when spiked. At times it has occurred while spiking and other times it has occurred after being spiked, spontaneously leaking.</p> 
<p>Type: Ventilator, Continuous, Minimal Ventilatory Support, Facility Use</p> <p><u>Brand:</u> Philips Respironics V60</p> <p><u>Model #:</u> V60 <u>Cat #:</u> V60</p>	<p>RESPIRONICS CALIFORNIA, LLC</p>	<p>Crack that is occurring in all our v60 BiPap ventilators. This crack is occurring on the top cover (part# 453561531971) above the proximal port. As I have researched this issue, I have found no evidence of physical abuse to the units, which prompted me to call Philips technical support. I spoke with a Philips technician and he stated that he has been aware of this issue for many years now and stated he thinks it is a result of using harsh cleaning agents. I spoke with the Respiratory staff regarding their cleaning procedures and they are in line with the manufacturers recommended cleaning methods. The price to replace the top cover is \$200 each. This is an issue since fluids can access the ventilators.</p>
<p>Type: Cable, Transducer And Electrode, Patient, (Including Connector)</p> <p><u>Brand:</u> AMC</p> <p><u>Model #:</u> LWM-329DS50/5A <u>Lot #:</u> AE220104</p>	<p>AMC</p>	<p>During procedure in Cardiovascular Operating Room (CVOR), the AMC 5 lead disposable was used. The only lead that gave a signal was III. This was attempted 2 more times, with 2 more devices, with the same results (all 3 devices had the same lot number).</p> <p>=====</p> <p>Manufacturer response for Cable, Transducer And Electrode, Patient, (Including Connector), AMC (per site reporter)</p> <p>=====</p> <p>Will obtain.</p>
<p>Type: Set, Administration, Intravascular</p>  <p><u>Brand:</u> Continu-Flo, Clearlink</p>	<p>BAXTER INTERNATIONAL INC.</p>	<p>Event 1: TPN/IL hung at 2145 and middle port on Baxter tubing noted to be leaking around 0100. Provider notified and new fluids ordered. Tubing saved and put in education office.</p> <p>Event 2: While assessing patient, liquid noted to be inside isolette by IV tubing. TPN tubing noted to be leaking from port closest to patient.</p> <p>Event 3: Baxter tubing hooked to PCVC leaking at port</p>

Device	Manufacturer	Problem
<p><u>Cat #:</u> 2R8546, 2C8519 <u>Other #:</u> Primary Administration Set 10 Drops/mL Drip Rate</p>		<p>closes to patient. Large puddle noted in isolette. Tubing changed out ASAP with new IVF bag and no further leaking noted. Patient's vitals remain stable. Labs sent this AM, to F/U on results. Medical team aware.</p> <p>Event 4: TPN hung at 930pm. At 515am pump rang alarm of upstream occlusion x2. RN picked up tubing to inspect and felt something was wet. Upon further inspection, leaking noted from second hub from top. TPN had to be discarded and clear IVF hung.</p> 
<p><u>Type:</u> Accessories, Blood Circuit, Hemodialysis</p> <p><u>Brand:</u> Crit-Line</p> <p><u>Cat #:</u> CL10041021 <u>Lot #:</u> 21KR01001</p> <p><u>Device Identifier</u> (DI)#: 00840861100552</p>	Fresenius USA, Inc.	<p>Sensor broke apart while the patient was on the HD machine causing a blood leak. Had we not noticed immediately and stopped the blood pump, patient would have major blood loss as this was leak in the circuit with a blood pump at 400 ml/min running. Minor blood loss to patient. The following day, another sensor was found not to be bonded together properly- caught prior to use.</p>

Establishment Registration & Device Listing:

This database includes medical device manufacturers registered with FDA and medical devices listed with FDA. It is updated monthly and contains [multiple links](#) to other FDA databases.

Global Unique Device Identification Database (GUDID):

A searchable database administered by the FDA which serves as a reference catalog for every device with a unique device identifier (UDI) and contains [additional GUDID](#) specific resources.

Human Factors Website:

A site providing information about human factors design, testing and use considerations. Other links include information about the [CDRH Human Factors Team](#) activities, including their contact information.

Medical Device Connectors Website:

A site providing information for healthcare professionals about hazards that occur when different device delivery systems are mistakenly connected to each other. [Examples](#) of misconnections, [additional resources](#), and other links reside on this site.

MAUDE (Manufacturer and User Facility Device Experience):

The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers. This site also contains links to [other FDA databases](#).

Medical Device Safety Website

One-stop for safety information with links to FDA medical device safety communications, recent letters to healthcare providers, recent medical device recalls, and [more device safety related links](#).

MedSun Website:

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)]:

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 web interface for more recent records. It is updated monthly and contains [multiple links](#) to other FDA databases.

Premarket Approvals (PMA):

The Premarket Approval (PMA) database of premarket approvals of Class III devices may be searched by a variety of fields and is updated monthly. This site contains [multiple links](#) to other FDA databases.

Product Classification:

This database can be used to determine the classification of a device and the regulations it is subject to. It has a list of all medical devices with their associated classifications, product codes, FDA Premarket Review organizations, and other regulatory information. [Multiple links](#) to other FDA databases are included on this site.

Warning Letters:

This database contains the most recent manufacturer warning letters. [Site](#) is searchable.

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