FDA NEWS RELEASE

FDA Roundup: August 30, 2024

For Immediate Release:

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Today, the U.S. Food and Drug Administration is providing an at-a-glance summary of news from around the agency:

- On Thursday, the FDA approved a new indication for ACAM2000 (https://www.fda.gov/vaccines-blood-biologics/vaccines/acam2000), to include the prevention of mpox disease in individuals determined to be at high risk for mpox infection. ACAM2000 has been approved since 2007 for the prevention of smallpox disease in individuals determined to be at high risk for smallpox infection. ACAM2000 is a live replicating vaccinia virus vaccine.

  Every person who receives ACAM2000 is required to receive the Medication Guide approved by FDA. A Medication Guide is necessary for safe and effective use of the vaccine because it could help prevent serious adverse events and inform the vaccine recipient of serious risks relative to benefit that could affect their decisions to be vaccinated.

- On Wednesday, the FDA granted marketing authorization for Renata Medical's Minima Stent System for the treatment of pulmonary artery stenoses and aortic coarctation (two congenital forms of narrowing of the arteries) in neonates, infants, and children at least 1.5kg in weight. This stent, which is designed to be periodically expanded over time to keep up with vessel growth, is designed specifically for infants to be approved in the US. This approval brings to market a less invasive treatment option for these vulnerable infants whose alternative treatment options until now have included cardiac surgery for repair of pulmonary artery stenoses and aortic coarctation.

- On Wednesday, the FDA posted four warning letters (https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters) issued to firms citing the sale of medical devices intended for cleaning, disinfecting, or sanitizing continuous positive airway pressure machines and accessories without marketing authorization from the agency. The safety and effectiveness of these devices has not been established. These devices therefore may be in violation of the Federal Food, Drug, and Cosmetic Act. After receiving a warning letter, a firm is expected to respond to the FDA within 15 business days and provide a

description of the specific steps it has taken to correct the violations noted in the warning letter and its plans to prevent these violations, or similar violations, from occurring again.

- On Wednesday, the FDA announced the Patient Engagement Advisory Committee (PEAC) meeting (https://content.govdelivery.com/accounts/USFDA/bulletins/3b154b5) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) that will be held virtually on October 30, 2024, 10 a.m.-5 p.m. ET. During this meeting, PEAC will discuss and make recommendations on patient-centered informed consent in clinical study of FDA-regulated medical products. The topics for discussion include the informed consent process and factors to consider when communicating informed consent to clinical study participants to increase the likelihood of participants understanding the key elements of research. Registration (https://www.fdalive.com/peac/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) is only required to participate in the breakout sessions.
- On Wednesday, the FDA authorized for marketing Germitec's Chronos, indicated for use in a healthcare environment for the high-level disinfection of surfaces of transvaginal, transrectal, and external ultrasound probes that do not contain internal passages or any indentations or channels that are deeper than their widths. This approval brings to market a chemical-free alternative and has a first-of-its-kind indication for use. After the probes have been cleaned, they are placed within the Chronos' chamber; once the chamber is closed, the probes are exposed to UV radiation for disinfection. This device is not intended for the cleaning or sterilization of ultrasound probes.

Related Information

- FDA Newsroom (https://www.fda.gov/news-events/fda-newsroom)

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, radiation-emitting electronic products, and for regulating tobacco products.

Inquiries

Media:

FDA Office of Media Affairs (mailto:fdaoma@fda.hhs.gov)

888-INFO-FDA

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