FDA wants stricter testing for defibrillators

January 21 2011, By MATTHEW PERRONE , AP Health Writer

(AP) -- The Food and Drug Administration is recommending stricter safety measures for heart-zapping defibrillators after years of increasing problems with the emergency medical devices.

Under the agency's proposal posted online Friday, makers of external defibrillators would need to submit more data and undergo manufacturing inspections before launching a new product.

The tighter regulation is aimed at curbing design and manufacturing flaws with the devices, which are found everywhere from hospitals to schools to airports. Medical device manufacturers have issued 68 recalls of defibrillators in the last five years, according to the FDA. And the agency has received more than 23,000 reports of device malfunctions, "including some where the device failure occurred during a rescue attempt and may have contributed to patient harm or death."

Defibrillators use electric shocks to jolt the heart back to normal after patients collapse from cardiac arrest.

The changes would not apply to implantable defibrillators, which are pacemaker-like devices given to patients with heart problems.

Next Tuesday the FDA will ask an expert panel to weigh in on its recommendations. The agency is not required to follow their advice.

Currently, makers of defibrillators are approved through an accelerated approval pathway designed for low-risk devices, which range from

hospital beds to artificial hips. The so-called 510(k) system allows speedy approval of devices that are similar to products already on the market. Regulators only inspect the companies' manufacturing facilities if they have cause to suspect a problem. Companies including Philips Healthcare, Cardiac Science Corp., Defibtech and others have petitioned the FDA to keep their devices approved at this standard.

But the FDA argues that stricter measures are needed because defibrillator makers have failed to fix problems that have led to the recall of hundreds of thousands of devices.

Under the FDA's proposal, device manufacturers would be subject to regular inspections and could be required to submit additional clinical data before launching a new version of their defibrillator. This is the current standard for implantable defibrillators, heart valves and other devices that help keep patients alive.

External defibrillators generally include two plastic pads that attach to the patient's chest and detect whether the heart is suffering an abnormal heart rhythm. If the problem can be corrected - which is the case about one-fourth of the time - the pads deliver an electric shock that resets the heart's pumping action.

Nearly 300,000 people in the U.S. collapse each year from cardiac arrest, according to the FDA. Academics estimate nearly 500 lives are saved each year in the U.S. as a result of bystanders using the devices.

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