

FDA Fact Sheets: Humanitarian Device Exemption (HDE)

A Humanitarian Use Device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 8,000 individuals in the United States per year. With HUDs, the research and development costs of the device could exceed the market returns. HUD regulations (21 CFR 814 Subpart H) provide an incentive for manufacturers to develop these devices for use in the treatment or diagnosis of diseases affecting these small populations.

A Humanitarian Device Exemption (HDE) application is submitted to FDA to obtain approval for an HUD and takes part in a two-step process. First, the company is required to file a humanitarian use device designation request. This request must be approved, over a period of 45 days, by FDA's Office of Orphan Products Development (OOPD) as meeting the statutory standards of an HUD.

Following review by OOPD, the sponsor submits an HDE application. This application is similar to a Premarket Approval Application (PMA) in both form and content, but is exempt from the effectiveness requirements of a PMA (i.e., it must demonstrate safety and probable benefit). Review of the application includes a 30-day filing period and a 75-day review clock. A review clock of 75 days is also used for review of HDE amendments, supplements and reports.

An HDE application is not required to include clinical investigation results to substantiate the effectiveness of the device; however, it must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use. The risk/benefit analysis must also take into account currently available devices or alternative forms of treatment and the risks and benefits that they provide. The applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that without the exemption they could not otherwise bring the device to market. If a comparable device is approved or cleared for the same indication as an approved HDE, FDA may withdraw HDE approval.

An HUD can only be used in a facility overseen by an Institutional Review Board (IRB). Labeling of an HUD is required to state that the device is a humanitarian use device and that, although the device is authorized by federal law, its effectiveness for the specific indication has not been demonstrated. However, an HUD may be used off-label in cases of an emergency situation (i.e., to save the life or protect the physical well-being of a patient) or for compassionate use.

The Quality System regulation (QS) applies to HDEs, but FDA primarily focuses on the manufacturing practices that relate to the safety of the device when implementing QS requirements, and a sponsor may request exemption from such requirements. HDEs must also follow Medical Device Reporting requirements.