















HDE At-a-Glance

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|  <p>What is the HDE pathway?</p> | <p>Humanitarian Device Exemption (HDE) is a FDA regulatory pathway for certain digital health products that are 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 - the FDA’s definition of a “rare” disease.</p> |
|  <p>What is the purpose of the HDE provision?</p> | <p>With high development and research investment costs compared to a smaller market and returns than products addressing more common diseases and conditions, this pathway exists to encourage the discovery and use of products intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect <8,000 individuals in the US.</p> |
|  <p>What is the criteria for the HDE provision?</p> | <ol style="list-style-type: none"> 1. The product will not expose patients to a significant risk of illness or injury, and the product’s probable benefit to health outweighs the risk of injury or illness from its use, while taking into account the probable risks and benefits of currently available products or alternative treatments 2. The product is not available to a person with the disease or condition in question without the HDE, and no comparable product is available to treat or diagnose such disease or condition 3. The product is intended to treat or diagnose a disease or condition that affects <8,000 individuals in the United States on an annual basis |
|  <p>When is an HDE typically required?</p> | <p>In order to receive marketing authorization under the HDE pathway, there are two steps:</p> <ol style="list-style-type: none"> 1. Prepare and submit a Humanitarian Use Device (HUD) designation request to FDA’s Office of Orphan Products Development (OOPD) 2. Submit an HDE application to receive marketing authority for the HUD |
|  <p>What is “Prohibition on Profit”?</p> | <p>As there are incentives provided by the FDA to facilitate the development of products for the pediatric population (age <22 years), after HDE approval, the product can only be sold if either:</p> <ol style="list-style-type: none"> 1. The product is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; OR |

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| | <p>2. The disease or disorder is for adult patients and does not occur in pediatric patients, or occurs in pediatric patients in such numbers that the development of the product for such patients is impossible, highly impracticable, or unsafe.</p> |
|  <p>How does the FDA monitor the product in the market?</p> | <p>The FDA keeps track of HDE products using the Annual Distribution Number.</p> <p>What is the Annual Distribution Number (ADN)?</p> <p>The number of HDE products that may be sold for profit is limited to a quantity known as the Annual Distribution Number. If the FDA determines that an HDE holder is eligible to sell the product for profit, the FDA will determine the ADN and notify the HDE holder. However, the ADN is not publicly available.</p> |
|  <p>How much does applying for the HDE provision cost?</p> | <p>No fee</p> |
|  <p>How long does the application process take?</p> | <p>75 days</p> |
|  <p>Where can I access HDE classified products?</p> | <p>Check out a list of legally marketed products in the HDE database.</p> |



Humanitarian Device Exemption (HDE)

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|  Search FDA HDE Database | <i>DiMe Resources</i> | | | |
| |  At-a-Glance |  Preparation Guide |  Checklist |  FAQs |

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