FAQs for **HDE**

Digital Health
Regulatory
Pathways

1 When does the FDA make the determination that the disease or condition affects or is manifested in not more than 8,000 individuals in the United States per year?

When an applicant makes a request for a Humanitarian Use Device (HUD), FDA makes its determination. You should submit your request for an HUD designation before submitting an application for an HDE. You should include the FDA's HUD designation letter in your application.

2 What is an orphan subset?

If the disease or condition occurs in more than 8,000 patients per year, the product could be used in a subset of the disease or condition as long as the sponsor shows the subset is an "orphan subset." An orphan subset is one in which use of the product is limited because of some inherent property of the product and/or the disease. The sponsor must explain why the product could not also be used in all patients with the disease or condition.

3 Can I directly apply for an HDE without receiving a HUD Designation?

No – Prior to submitting an HDE application, an applicant must first obtain HUD Designation to ensure the population estimate to qualify is "no more than 8,000."

4 Where do I submit the HUD application?

Applicants who wish to obtain HUD designation should submit one original paper copy and one duplicate copy (another paper copy or an electronic copy on compact disc) to the following address:

Office of Orphan Products Development
Food and Drug Administration
10903 New Hampshire Ave., WO32-5295
Silver Spring, MD 20993

5 Who can I contact if I have questions about the HUD application?

For any and all questions, contact the Office of Orphan Products Development:

Telephone: 301-796-8660 Fax: 301-847-8621 Email: orphan@fda.hhs.gov

6 How does the FDA calculate the Annual Distribution Number (ADN)?

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.

The ADN is calculated by taking the number of devices reasonably necessary to treat or diagnose an individual per year and multiplying it by 8,000. For example, if the typical course of treatment using an HDE device, in accordance with its intended use, requires the use of four products per patient per year, then the ADN for that HDE device would be 32,000 (i.e., 4 x 8,000).

7 I am developing a combinational digital health product, can I apply for an HDE?

If your product is part of a combination product, an HDE may not be the appropriate pathway to market.

- For questions about the availability of the HDE pathway for combination products, contact the Office of Combination Products (combination@fda.gov).
- For questions about Companion Diagnostic Devices, contact Center for Devices and Radiological Health's Office of Health Technology/Office of In Vitro Diagnostics and Radiological Health (oir-policy@fda.hhs.gov).

8 How long does the FDA take to review the HDE application?

The review timeframe for HDE applications is **75 days**. In addition, if the applicant submits a major amendment, the review timeframe may be extended up to 75 additional days. Certain changes to the manufacturing procedure or changes in method of manufacture may qualify to be submitted as a 30-day notice. Learn more here.

9 Is there a fee associated with an HDE request?

No – There is no fee associated with an HDE request.

10 Are there pediatric products that HDE approved to be "sold for profit"?

Yes – You can find more information here about the pediatric Humanitarian Device Exemptions approved to be sold for profit that are reviewed by the Pediatric Advisory Committee (PAC).

Humanitarian Device Exemption (HDE)

Search FDA HDE Database

DiMe Resources

At-a-Glance

Preparation Guide

Checklist

FAQs

Access DiMe's Digital Health Regulatory Pathway Resources

Identify your regulatory pathway

Build your regulatory strategy

Interact with regulators