Medical Device User Fee Amendments (MDUFA) - Foreign Small Business Qualification and Certification

Part 48-01-01

This document outlines the circumstances in which a US company based in Ireland may qualify and be certified as a 'small business' in order to avail of reduced Premarket Application fees charged by the US Food and Drugs Administration

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1. Overview

The US Food and Drugs Administration (FDA) has guidelines in place for foreign countries, including Ireland, where businesses can avail of reduced pre-market application (PMA) fees based on the turnover of the company. This means significant savings for some Irish medical technology companies. In the past only US-based companies could avail of this reduced fee because they were able to file federal tax returns. Companies outside the US are now allowed to submit certified annual sales through their tax returns and receive the same benefits.

The US FDA has clarified that businesses headquartered outside the United States can qualify as a "small" business if they have "gross receipts or sales" of no more than $100 million for the most recent tax year, including the gross receipts or sales of all their affiliates. The certification is on an annual basis – based on a year from 1 October to 30 September.

A company may obtain a one-time waiver of the fee of their first (ever) pre-market application (pre-market approval application, biologics license application, product development protocol or pre-market report). To qualify for this fee waiver, they must qualify as a "small business" with gross receipts or sales of no more than $30 million, including the gross receipts or sales of all their affiliates.

In either case, whether a US company in Ireland is applying for reduced PMA fees or for a one-time waiver, the only requirement arising for Revenue staff is to certify the level of company turnover as per our records.

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