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AcuCort granted renewed FDA Small Business Waiver – Important milestone ahead of planned NDA submission in 2026

The U.S. Food and Drug Administration (FDA) has granted AcuCort's application for a renewed Small Business Waiver (SBW). The decision exempts the company from the application fee for its planned New Drug Application (NDA), a fee that would otherwise amount to approximately SEK 16 million.

The FDA had previously granted AcuCort a Small Business Waiver (SBW). As the previous waiver had expired, the company applied for a renewal earlier this year, which has now been approved by the FDA. In April 2026, AcuCort also announced that it had reached agreement with the FDA that no additional studies are required prior to submitting its NDA.

"With both the iPSP agreement and the renewed Small Business Waiver now in place, we remain on schedule. If everything proceeds according to plan, we expect to submit our NDA later this year," says Jonas Jönmark, CEO of AcuCort.

An NDA is typically reviewed within approximately 12 months. Through the renewed Small Business Waiver, AcuCort is exempt from the application fee of approximately SEK 16 million.

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About AcuCort AB (publ)

AcuCort has developed and is commercializing Zeqmelit®, a new rapidly dissolving oral film placed on the tongue, based on the well-known cortisone substance dexamethasone. The drug is a smart product in a new, innovative, patented, and user-friendly administration form primarily for the treatment of severe and acute allergic reactions, croup in children, nausea and vomiting during chemotherapy, and for the treatment of patients with COVID-19 requiring supplemental oxygen therapy. Zeqmelit® is approved in Sweden, Denmark, Norway, and Finland, where the product is also marketed. AcuCort (ticker: ACUC) is listed on the Spotlight Stock Market. Visit www.acucort.se for more information.