ASX Release

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Positive FDA Remote Regulatory Assessment

Melbourne, Australia; Acrux Limited (ASX:ACR)

Acrux is pleased to confirm the favourable outcome of a Remote Regulatory Assessment (RRA) carried out by the U.S. Food and Drug Administration (FDA).

The FDA have completed an RRA of Acrux concluding that… *"During the current RRA we did not identify objectionable conditions and thus do not have any observations…"*

The FDA RRA was carried out by the Division of Generic Drugs Study Integrity (DGDSI), Office of Study Integrity and Surveillance (OSIS), which forms part of Center for Drug Evaluation and Research (CDER). As part of the FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs.

The RRA was based on an in-vitro bioequivalence study that Acrux conducted and submitted to the FDA as part of an Abbreviated New Drug Application (ANDA) that is currently under FDA review.

Authorised for release by the Board of Acrux Limited.

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About Acrux

Acrux is a specialty pharma company with a successful track record of developing and commercialising a pipeline of topically applied pharmaceutical products. Drawing on 25 years of experience, Acrux has successfully marketed through licensees a number of products worldwide with emphasis on the United States. Acrux is formulating and developing a range of topical generic products by leveraging its highly skilled workforce, on-site laboratories, GMP manufacturing suite, technical, clinical and commercial experience to bring affordable products to market. Acrux encourages collaboration and is well positioned to discuss commercial partnering and product development opportunities. For further information on Acrux, visit www.acrux.com.au

About Remote Regulatory Assessment (RRA)

An RRA is an examination of an FDA-regulated establishment and/or its records, conducted entirely remotely, to evaluate compliance with applicable FDA requirements. RRAs assist in protecting human and animal health, informing regulatory decisions, and verifying certain information submitted to the Agency.

RRAs are a tool FDA may use to support regulatory decisions and oversight activities. RRAs that are not conducted under statutory or regulatory authority are voluntary in that an establishment can decline to participate or withdraw participation during the RRA, in which case the Agency would consider other tools for evaluating compliance with FDA requirements.

RRAs complement FDA's authority to conduct inspections under section 704(a)(1) of the FD&C Act and other applicable FDA authorities. RRAs do not limit the authority of FDA to conduct inspections under section 704(a)(1) of the FD&C Act and other applicable FDA authorities.

Source: https://www.fda.gov/media/160173/download