



STATEMENT

To Generic Drug Manufacturers Considering Retiring or Withdrawing ANDAs for Essential Medicines: Civica Rx Is Interested

SALT LAKE CITY, UT, January 14, 2020 – [Civica Rx](#) (Civica, Inc.) today announced that it is interested in talking to generic drug manufacturers who are considering retiring or withdrawing their Abbreviated New Drug Applications (ANDAs) for essential medicines that are at risk of being in short supply.

Periodically, the FDA withdraws approvals of ANDAs due to manufacturer inactivity. According to published reports, the FDA is considering withdrawing close to 250 ANDAs for these reasons.

“Part of our manufacturing strategy is to develop our own ANDAs for essential medications and that work is underway,” said Martin VanTrieste, President and CEO of Civica Rx. “However, developing new ANDAs takes time and we’d be very interested in taking over existing ANDAs for essential medications that have a history of drug shortages. This could be a win-win-win for Civica, current ANDA holders and, most importantly patients who will need these medications in the future.”

“Civica stands ready to take over some of these ANDAs, which the ANDA holders could donate to Civica for potential tax deductions,” VanTrieste added. By donating their inactive ANDAs, these manufacturers will help ensure patients have quality medications that are available and affordable well into the future.”

Civica was founded in 2018 by leading US hospital systems concerned about generic drug shortages and philanthropic organizations passionate about improving healthcare. To date, nearly 50 health systems are Civica members, representing more than 1,200 US hospitals and over 30 percent of all licensed US hospital beds. [Civica currently has 18 medications in production and/or shipped](#) for use in hospitals across the country.

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More About Civica Rx

Civica aims to stabilize the supply of essential medications. It is actively pursuing a three-pronged product supply strategy:

- Working with multiple generic drug manufacturers that have the US FDA approved manufacturing facilities and capacity to produce generic drugs under Civica’s National Drug Code, allowing manufacturers to re-enter the market or increase existing capacity. Civica is currently working with five quality supplier partners, including Xellia Pharmaceuticals and Hikma, and is in negotiations with several more.
- Developing Abbreviated New Drug Applications (ANDAs) for generic drugs and working with contract manufacturing organizations to produce Civica medications.
- Acquiring/building Civica manufacturing facilities using Civica's ANDAs.

Find more information about Civica Rx at www.civicarx.org.

CONTACT: Debbi Ford, Debbi.ford@civicarx.org