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FOR IMMEDIATE RELEASE

STRATUS PHARMACEUTICALS', TARMAC PRODUCTS, INC., MIAMI GARDENS FACILITY RECEIVES FDA INSPECTION RESULTS

Miami, Fla. – March 28, 2018 – Stratus Pharmaceuticals, Inc. and Tarmac Products, Inc. are pleased to announce that the U.S. Food and Drug Administration (FDA) inspected the Miami Gardens manufacturing facility and found it to be GMP (Good Manufacturing Practices) compliant.

Tarmac can now apply for New Drug Applications (NDA) and Abbreviated New Drug Applications (ANDA) without opposition from the FDA.

"This is a major milestone for Stratus and Tarmac," said Alberto Hoyo, President of Stratus Pharmaceuticals. "We are committed to continuing to produce and distribute high-quality products for our longstanding clients."

On April 28, 2017, Stratus Pharmaceuticals finalized the closing of its New Jersey manufacturing facility and ceased manufacturing certain products. As a result, the following took place:

1. Tarmac Products, Inc. took over all manufacturing of Stratus products.
2. There were **NO** recalls for any Stratus products.
3. There were **NO** interruptions in manufacturing and shipping of Stratus products.*
4. The Stratus Distribution Center in Miami, Fla. continues to be fully operational.
5. The Florida-based manufacturing facility (*Tarmac Products, Inc., Miami Gardens, Fla.*) is fully operational and in conformance with the U.S. Federal Food, Drug, and Cosmetic Act.

"Stratus Pharmaceuticals continues its commitment to improving its products and increasing its production capabilities," added Hoyo. In early 2013, the company acquired its Miami Gardens manufacturing facility located near its distribution center in South Florida. The 60,000 square foot-plant is a climate-controlled facility manufacturing topicals, powders, suppositories, and eventually solid dosages.

"Stratus has invested time and finances to convert Tarmac Products, Inc. into a state-of-the-art facility," said Hoyo. "We are immensely pleased that the FDA has given us its stamp of approval."

Tarmac Products' laboratory was also upgraded and modernized by adding state-of-the-art equipment, including **Biolumix** for rapid in-house microbiology testing.

ABOUT STRATUS

Stratus Pharmaceuticals, Inc. operates as a pharmaceutical company that provides dermatology, plastic surgery, wound care, and podiatry products.



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Stratus Pharmaceuticals Responds to Misinformation In the Aftermath of FDA Consent Agreement

Miami, Fla. – June 19, 2017 – In order to clarify misinformation disseminated as a result of the Consent Decree entered by the Southern District of Florida, and to which Stratus Pharmaceuticals agreed Stratus advises that its decision to enter into that agreement was strictly economic – and in no way an admission of the specific allegations in the FDA's Complaint.

In fact, none of the allegations in the Complaint have been established by testimony or evidence, and many are factually inaccurate. For example, Alberto Hoyo was not the President or CEO of Sonar Products Inc., at the time of the inspections that gave rise to the FDA enforcement action, as the Complaint claims. The inspections that led to this enforcement action took place during the tenure of Sonar's former president, who was terminated. He was replaced by a highly qualified and experienced executive in the industry.

It is important to point out the following items in this Consent Decree:

1. There is **NO** recall for any of Stratus' products.
2. Stratus' Miami Gardens manufacturing facility continues to operate without any interruptions in conformance with the Federal Food, Drug and Cosmetic Act.
3. There will be **NO** interruptions in manufacturing and shipping of our products.
4. The Stratus Distribution Center in Miami continues to operate without any disruptions.
5. Stratus discontinued the manufacturing and distribution of unapproved products.

It should be noted that the FDA did not act with any urgency on this matter. Their action was based on inspections that took place more than two years ago. Also, since the inspections in 2015, the FDA never returned to Stratus or Sonar to conduct additional inspections. There were never any subsequent negative findings. On the contrary, independent auditors agreed that both facilities were in substantial compliance with current good manufacturing practice (CGMP) requirements.

"We are looking forward, not backwards," said Mr. Hoyo. "We agreed to the terms of the Consent Decree only in order to close the chapter of its association with Sonar."

Stratus has moved all of its production to a state-of-the-art facility in South Florida where it will continue to produce and distribute the highest-quality products for its longstanding clients.

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