



Contact: Olga Suarez Vieira, Attorney for Stratus Pharmaceuticals, ovieira@carltonfields.com or (305) 539-7379

FOR IMMEDIATE RELEASE

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.

ABOUT STRATUS

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