NEWS RELEASE

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Chemi Nutra’s Brazilian Production Facility Passes Rigorous FDA Inspection

White Bear Lake, MN – Paolo Oligeri, President, Chemi S.p.A., Milan, Italy, proudly announces that Chemi’s manufacturing facility, ITF Chemical Ltda., Camacari, Bahia, Brazil, has been inspected by the Department of Health & Human Services, Public Health Service, of the Food and Drug Administration (FDA), and has been granted acceptable status under FDA’s strict inspection guidelines, as notified on June 16, 2009. Chemi has been manufacturing SerinAid® PhosphatidylSerine (PS) and other specialty nutrition ingredients used in dietary supplements and functional foods in this current good manufacturing practices (cGMP) compliant facility.

Since its acquisition of this plant in 2000, Chemi has invested heavily in the modernization and expansion of this Brazilian plant, now fully dedicated to production of active pharmaceutical ingredients (APIs) and nutraceutical ingredients. This successful inspection completes a final round of FDA inspection audits that included Chemi’s other production facilities located in Cinisello Balsamo and Patrica, Italy.

Over the past few years, this Brazilian facility has experienced a number of plant expansions, including the construction of new R&D and QC facilities, a new plant for API manufacture, and a new warehouse. The opening of new lines for PS production (standard and identity preserved) and a complete upgrade of drying and milling rooms was included in those expansions. Overall, Chemi’s total PS production capacity doubled by 2005, and witnessed another 50% increase soon after, allowing Chemi to respond with greater flexibility and efficiency to the growing demand for PS and other nutraceutical ingredients.

The FDA provided an Establishment Inspection Report (EIR) to Chemi at the conclusion of this inspection, in the FDA’s quest to work diligently in making the regulatory process more transparent. Chemi has publicly stated that it will continue in its efforts to ensure continued compliance with cGMPs.

Scott Hagerman, president of Chemi Nutra said, “We are again very pleased that our Brazilian manufacturing facility has passed another round of FDA inspections with flying colors. All of our customers can rest assured that our SerinAid® PhosphatidylSerine (PS) and other specialty nutrition ingredients used in dietary supplements and functional foods, are manufactured in state-of-the-art FDA inspected production facilities, and well within all applicable GMP regulations now in place in the nutritional products industry.”
Chemi Nutra is the US business unit of parent company Chemi S.p.A., a privately held pharmaceutical and nutraceutical company based in Milan, Italy. Chemi, with cGMP certified manufacturing facilities in Italy and Brazil, is best known in the US nutritional arena for its introduction of phosphatidylserine (PS), the popular dietary supplement which has been granted two qualified health claims by the FDA, and is used to enhance learning, memory, and concentration, exercise performance, and youthful wellbeing, and to reduce stress.