Tegra Analytics, LLC

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FDA approves New Drug Application based on four clinical trials

March 30, 2006

Columbia, SC. Tegra is pleased to announce the approval of a New Drug Application (NDA #022010) for *Septocaine® with epinephrine 1:200,000*. Four clinical trials spanning three years culminated in a letter of approval from the FDA today. Tegra Analytics provided a comprehensive range of statistical services beginning with the initial design of the Phase II/III trials, collecting data from the case report forms and submitting statistical analyses to the FDA. The sponsor, Novocol Pharmaceutical of Canada, Inc., stated,

> *"Septocaine® 1:200,000 has been approved with no 483s and within the 6 month review cycle for an NDA and a large part of that is due to excellent study design, good statistics and quality data. It was a genuine pleasure working with Tegra and I hope we get a chance to collaborate again in the future."*

Tegra Analytics, LLC., located in Columbia, SC, and Doylestown, PA, offers custom, accurate and straight-forward analytical products and services. Tegra works with the physicians, Sponsor and FDA to design the statistical components of the protocols, create the statistical analysis plan and analyze the clinical data to deliver a thorough FDA submission.

Tegra's Role

Throughout the design, analysis and approval process, Tegra provided the following services:

- Protocol review
- Research prior studies and submissions
- Construct optimal study designs
- Provide appropriate hypotheses and perform inferential statistical analyses
- Develop efficacy criteria (primary and secondary)
- Review safety considerations
- Develop data collection procedures and data storage capabilities
- Provide patient selection randomization procedures, power calculations, cost considerations, sample size calculations and statistical procedures
- Assist with data management, case report forms, provide all data entry and QA
- Attend several meetings in Washington, DC with PI, Sponsor, FDA and law firm
- Documentation of SAS data and procedures
- Statistical documentation for final clinical reports and Section 8 (safety) submitted to FDA
- Review documents and QA every number transcribed by Sponsor
- Assist with supplemental FDA requests during the approval process

Further Information

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