



NDA 20-920/S-012

Scios Inc.
Attention: Stephanie Sassman
Manager, Regulatory Affairs
6500 Paseo Padre Parkway
Fremont, CA 94555-3658

Dear Ms. Sassman:

Please refer to your supplemental new drug application dated June 28, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Natrecor (nesiritide) for Injection.

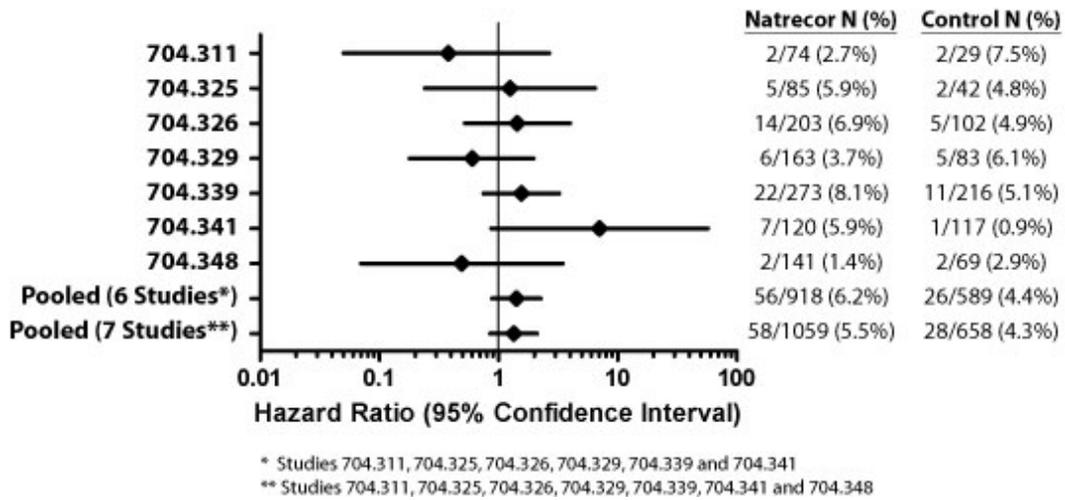
This supplemental new drug application provides for labeling revised as follows:

1. The **ADVERSE REACTIONS/Effect on Mortality** has been revised and now reads as follows:

Data from all seven studies in which 30-day data were collected are presented in the chart below. The data depict hazard ratios and confidence intervals of mortality data for randomized and treated patients with Natrecor[®] relative to active controls through day 30 for each of the 7 individual studies (Studies 311, 325, 326, 329 [PRECEDENT], 339 [VMAC], 341 [PROACTION], and 348 [FUSION I]).

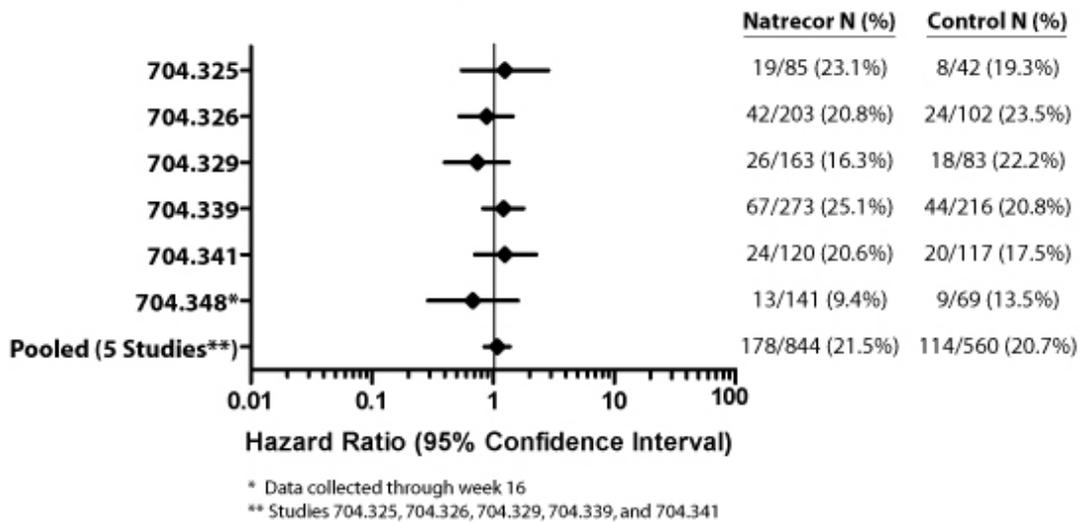
The figure (on logarithmic scale) also contains a plot for the six studies involving hospitalized or Emergency Department patients combined (n = 1507), and for all 7 studies combined (n = 1717). The percentage is the Kaplan-Meier estimate.

30-Day Hazard Ratios



The figure below represents 180-day mortality hazard ratios for randomized and treated patients from all five individual studies where 180-day data were collected, 16 week hazard ratios for Study 348 (180-day data were not collected), and the five studies with 180-day data pooled (n = 1404).

180-Day Hazard Ratios



There were few deaths in these studies, so the confidence limits around the hazard ratios for mortality are wide. The studies are also small, so some potentially important baseline imbalances exist among the treatment groups, the effects of which cannot be ascertained.

2. The copyright date and item number have been revised.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the submitted content of labeling [21 CFR 314.50(l)] in structured product labeling format (content of labeling submitted June 28, 2006).

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Russell Fortney
Regulatory Health Project Manager
(301) 796-1068

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Norman Stockbridge
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