Chester Labs

The Professional Advantage

September 18, 2001

Dockets Management Branch (HFA-305)
Docket No. 78N-036L
Food & Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Sir or Madam:

In response to the FDA's request for all reported adverse drug expenses, three (3) were reported to Chester Labs in the last ten (10) years, 1991-2001. Below are summaries for each of the adverse drug experiences.

December 1993 – Reported by Carl's Drugs Ltd.; Castlegar, British Columbia, Canada

A female child with a known history of allergies was administered Chester's Gent-L-Tip Enema, product number 101503. The child had been admitted to the hospital for an unrelated issue and received the enema. Shortly after the enema was given, the little girl experienced a severe allergic reaction and had difficulty breathing. The patient was fully recovered and released the following day.

May 1994 – Reported by Cambridge Medical; Fairfield, Connecticut

An adult patient was administered Chester's Gent-L-Tip Enema, product number 101503, and then experienced rectal bleeding of 5cc. The patient was scoped by a specialist and a tear and puncture were observed. This was attributed to the administration of the enema.

January 1998 – St. Luke's Hospital; Cedar Rapids, Iowa

An adult male patient at the hospital received a Baxter Enema product #20306-010, in preparation for a medical procedure. The patient complained of abdominal pain immediately after the enema was administered. The scheduled procedure was performed, and the scope detected a rectal laceration attributed to the administration of the enema. The patient was admitted to the hospital on 12/19/97, treated with antibiotics and observed. On 12/21/97, the gentleman was released. The patient had a follow-up visit with his physician and was reported to be fine.

Please feel free to contact me if you have any further questions.

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Sincerely,

Holly Sherwood
Quality Assurance Manager

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