



24 September, 2003

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 00N-1484
Safety Reporting Requirements for Human Drug and Biological Products

Dear Sir/Madam:

We appreciate the opportunity to review and comment on the proposed rule for "Safety Reporting Requirements for Human Drug and Biological Products." Please find attached detailed comments on various aspects of this proposed rule. We hope you find these comments useful toward the efforts to further improve and harmonize the safety reporting requirements.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Buchanan", written over a horizontal line.

James Buchanan, Pharm.D.
Director, Drug Safety & Surveillance
Tularik Inc.

00N-1484

C6