[Date]

Food and Drug Administration
Center for Drug Evaluation and Research
Division of [Assigned Therapeutic Area] Products
Attn: [FDA Contact], MD
5901B Ammendale Road
Beltsville, MD 20705-1266

RE: IND XX,XXX, Serial Number 00XX
[IP Proprietary Name]® [IP Generic Name], USP
IND Safety Report

Dear Dr. [FDA Contact]:

In accordance with 21 CFR 312.32, we are submitting this IND Safety Report for the above referenced IND XX,XXX for use of [investigational product] in the treatment of [disease or condition].

The report [Protocol Number] SAE XXX-XXX 2009_MMDD describes the adverse event of [event term] requiring hospitalization and treatment with [describe treatment] that occurred in X patient(s). The patient was participating in the clinical protocol [Protocol Number] entitled: "[Full Protocol Title]." The event was classified as serious, unexpected, and possibly related to the study agent, [IP]. The information, received on [Date], is incorporated in the attached MedWatch Form (FDA 3500A). A copy of the IND Safety Report will be sent to all [Protocol Number] clinical trial investigators, to the Data Safety Monitoring Board, and to the manufacturer [Manufacturer Name].

The [IND Holder] database was searched for all safety reports previously filed with the IND concerning a similar serious adverse experience. The search [did] [did not] identify any similar reports. [If similar reports were identified, the medical monitor provides analysis and discussion.]

The event has been classified as possibly related to the study agent, [IP], as [discuss reasoning and provide citations]. The treatment allocation remains blinded.

[Event term] is not listed among the adverse events in the [labeling] [Investigator's Brochure] for [IP], so the event has been classified as unexpected.

If you have any questions, please feel free to call me at (XXX) XXX-XXXX.

Sincerely,

[IND Holder Name and Credentials]
[IND Holder Title]
[Institutional Affiliation]

cc: file
submitted in triplicate: *Form FDA 1571*
Form FDA 3500A