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July 18, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Draft Guidance for Industry: Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials
[Docket No. 2005D-0155, 70 FR, 22665, May 2, 2005]

Dear Dockets Management:

DynPort Vaccine Company, LLC (DVC) appreciates the opportunity to comment on this important new guidance, which provides detailed recommendations regarding the toxicity grading scale proposed for use in vaccine studies in healthy adult and adolescent volunteers. Our comments are detailed below.

General Comment:

Comment 1: DVC would like the agency to consider expanding on the toxicity grading scale guidance by providing grading scales based on age ranges (e.g., 18-30, 31-45, >45, and pediatric and geriatric age groups) as opposed to providing a single toxicity grading scale for healthy adults and adolescent volunteers.

Section IIIA. Tables for Clinical Abnormalities:

Comment 2: The Vital Signs toxicity grading scale table lists values for Mild (Grade 1) toxicity for bradycardia of 50-54 beats per minute and for respiratory rate of 17-20 breaths per minute. Healthy adults and adolescents, particularly athletes or physically fit individuals, may have resting heart rates in the range of 40-50 beats per minute and respiration rates in the range of 16-20 breaths per minute reflecting normal physiologic conditioning.

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Recommendation: Consider expressing the ranges for toxicity in terms of changes from baseline for these parameters as was done for certain parameters in the Serum toxicity table.

Comment 3: In the Systemic (General) toxicity grading scale table for Mild (Grade 2) Headache, please clarify what the Agency considers to be “repeated” use of a non-narcotic pain reliever. For example, would two Tylenol taken four hours apart be considered a Grade 2 toxicity if there is no interference with activity?

Recommendation: Consider rewording the definition of Moderate (Grade 2) toxicity for headache to:

“Some interference with activity with repeated use of non-narcotic pain reliever”

If there are any questions regarding these comments, please contact Kathy Watson at 301-607-5032 or kwatson21@csc.com.

Sincerely,



Kathy Watson
Sr. Manager, Regulatory Affairs
DynPort Vaccine Company LLC – A CSC Company