EXHIBIT C

Guidance for Industry

Q1E Evaluation of Stability Data

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

June 2004
ICH

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Q1E Evaluation of Stability Data

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U.S. Department of Health and Human Services
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I. INTRODUCTION (1.0)[2]

This guidance provides recommendations on how to use stability data generated in accordance with the principles detailed in the ICH guidance Q1A(R2) *Stability Testing of New Drug Substances and Products* (parent guidance) to propose a retest period or shelf life in a registration application. This guidance describes when and how extrapolation can be considered when proposing a retest period for a drug substance or a shelf life for a drug product that extends beyond the period covered by available data from the stability study under the long-term storage condition (long-term data).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The recommendations in the evaluation and statistical analysis of stability data provided in the parent guidance are brief in nature and limited in scope. The parent guidance states that regression analysis is an appropriate approach to analyzing quantitative stability data for retest

[1] This guidance was developed within the Expert Working Group (Quality) of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and has been subject to consultation by the regulatory parties, in accordance with the ICH process. This document has been endorsed by the ICH Steering Committee at *Step 4* of the ICH process, February 2003. At *Step 4* of the process, the final draft is recommended for adoption to the regulatory bodies of the European Union, Japan, and the United States.

[2] Arabic numbers reflect the organizational breakdown in the document endorsed by the ICH Steering Committee at Step 4 of the ICH process, February 2003.

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