



FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

Memorandum

Date: March 20, 2013

To: Scott Greenfeder, Ph.D.
Associate Director, Regulatory Affairs
Merck & Dohme Corporation
Rahway, NJ 07065

From: Captain Colleen Sweeney, R.N., M.S.

Subject: BLA 125473.0

We wish to inform you, that we have reconsidered the advice conveyed to you at the December 3, 2001, pre-IND Meeting for “Timothy Grass (*Phleum pretense*) Allergenic Extract Tablet Form, (Grazax,), ALK-Abello, A/S, Horsholm, Denmark.”

Specifically, we have reconsidered our comment, “*Labeling the product with unitage other than that currently used in the United States (U.S.), would not be acceptable.*”

Please note that we now consider it acceptable to label the product in units other than that used in the U.S., such as Standardized Quality units Tablet (SQ-T). However, we request that the package inset include a description of the range in equivalent potency U.S. unitage, such as bioequivalence allergy units (BAU).