



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND  
TOXIC SUBSTANCES

September 14, 2009

NOTE TO RM 10 Bonaventure Akinlosotu

SUBJECT: Compliance with Child-Resistant Packaging Regulations EPA FILE NO:65331-2 DP 368668, Decision # 404722

Please note that EPA FILE NO: 65331-2 directions for the CRP blisters used in December 8, 1998 CRP testing (MRID 447491-01, 447491-02, 447491-03) are **not** the same as the directions on the April 13, 1999 accepted label **nor** are they the same as the last accepted label October 24, 2003. Therefore, EPA FILE NO: 65331-2 is **not in compliance with the CRP regulations**. The regulations in 16 CFR1700.20 (a)(3)(iv) indicate the senior adults shall receive the CRP directions as they will be on the package delivered to the consumer. Additionally, these directions should be the same in all locations on the CRP blister, any package inserts, and the outer carton.

The Agency should have noted this discrepancy and corrected it in 1999. The registrant was advised of this issue in July 16, 2009 correspondence and the June 23, 2009 CRP review. The Agency inadvertently failed to correct the problem. **All products must be in compliance with the CRP regulations and be labeled in all locations (CRP blister, any package inserts, and the outer carton) with the directions for the CRP blisters used in December 8, 1998 CRP testing (MRID 447491-01, 447491-02, 447491-03) .**

Please place a copy of this note in the registration jacket for the above named product. Please advise the registrant, accordingly. If you have any questions please contact me at (703)-308-7368.

A handwritten signature in cursive script that reads "Rosalind L. Gross".

Rosalind L. Gross