LOG OF MEETING

SUBJECT: International Organization for Standardization (ISO) voluntary standards meeting (ISO/TC 122/SC3/WG3) on Child Resistant Packaging Test Methods.

DATE OF MEETING: 09/15-16/97

PLACE: REALCOOP Ltd., Tesnov 5, 110 01 Prague , Czech Republic.

LOG ENTRY SOURCE: Charles J. Wilbur, EHHS

COMMISSION REPRESENTATIVES:

Charles J. Wilbur, EHHS

NON-COMMISSION REPRESENTATIVES:

International Organization for Standardization (ISO), ISO/TC 122/SC3/WG3 Committee Members, e. g., representatives from Denmark, Germany, United Kingdom, Belgium, Canada, etc.

SUMMARY OF MEETING: (Minutes of meeting available from Mr. Wilbur)

The meeting objective was to harmonize the U.S. (PPPA) and ISO standards to facilitate trade between countries, while maintaining child resistant effectiveness. To accomplish this ISO members are to vote on the adoption of the U.S. (PPPA) protocol in ISO 8317 (CRP Requirements and Testing Procedures Reclosable packages) and CEN Draft EN 862 (CRP Requirements and Testing Procedures Non-Reclosable packages for Non-Pharmaceutical Products, e.g. blister, pouches, etc.) be adopted as an ISO standard.

See attached for meeting resolutions (6).

International Organization for Standardization (ISO)
ISO/TC 122/SC3/WG3 Committee, September 15, 1997.

RESOLUTIONS

1. The WG recommends that EN 862 be put forward for adoption as an ISO standard.

2. The WG recommends that a vote be put to ISO members that the USA adult test protocol be adopted as the adult test method in ISO 8317.

3. The WG feels that Annex A should be part of the ISO 8317 standard but it needs rewriting to reflect exactly what it means, to include a rational and to explain more precisely the effect of shape and size of a series of CR pack.

4. Para 3.1 of 8317 needs rewording to give more specific details of what constitutes actual data which shows the ongoing production meets child resistant parameters set by the testing protocol.

5. The WG is to provide a rational to section 5.2 why 1 liter of substitute product is specified.

6. The WG will wait for a CEN standard for non-reclosable pharm products but to facilitate the work of the CEN WG; each delegate will produce and submit to the convenor for circulation a document covering their requirements for:

a) A rational for the standard (for/against)
b) Applicable standards
c) Potential area of conflict
d) Type of standard required
e) Advantages/Disadvantages
f) Links with current Legislation