Antimicrobial Product Labeling

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Presented To:

PPDC

Presented By:

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EPA/PPDC Alternative Testing Project

- **Origin**: Initiated by EPA/OPP Director Jim Jones following discussion with Bill Stokes and OPP's Federal Advisory Committee (PPDC).
- **Goal**: Consider adoption of non-animal methods to the Draize methods for acute eye and skin irritation for a narrow class of OPP regulated products.
- **Sector Specific**: Project scope limited to antimicrobial cleaning products only-comparatively robust data base.
- **Narrow Regulatory Purpose**: Allow EPA reviewers to make Toxicity Category and Product Labeling decisions based upon these alternative assays.

Overview

Anti-Microbial Cleaning Products,
e.g. Mr. Clean, Febreze, Scrubbing Bubbles, Windex Anti-Microbial

Non-Animal Hazard Evaluation,
e.g. formulation analysis, in vitro test information

EPA Labeling Categories,
e.g. CAUTION (Toxic Category III eye irritant)

Plan of Action

- Gather extant data on eye and skin irritation
- Both animal and non-animal tests
- Fill in gaps
- Develop Background Review Document for ICCVAM review

Participants

Eight companies:

- Clorox
- Colgate Palmolive
- Dial
- EcoLabs
- JohnsonDiversey
- P&G
- *Reckitt Benckiser*
- SC Johnson

have submitted data and will assist the program in various ways.

Non-Animal Assays

Anticipated non-animal assays for eye:

- Cytosensor™ assay; Real time information on cytotoxicity to monolayer cells – Mild/Moderate end
- EpiOcular™ assay; Engineered 3-D model (human tissue) of corneal epithelium – Mild/Moderate end
- Bovine Cornea Opacity and Permeability (BCOP) Assay; Discarded bovine corneas from slaughter houses provide organotypic tissue – Moderate/ Aggressive

Non-Animal Assays

Anticipated non-animal assays for skin:

- EpiDerm™; Engineered 3-D model (human tissue) of epidermis; OECD Guideline for corrosivity and EPA performance standard document
- Where appropriate, human skin compatibility, e.g. 4hr patch test

Progress

- Confidentiality has been ensured. No data in the submission will be traceable to an individual company.
- Database has been constructed and ~330 animal studies (280 with full information), and ~500 in vitro studies (~160 paired with animal data) have been entered by bucket.
- A determination of general testing strategy has been made.
- A number of “gap-filling” studies have been completed and others are underway, mainly with BCOP and EpiOcular.
- The Background Review Document (BRD) is being prepared for ICCVAM review.

Path Forward

- Briefed ICCVAM Ocular and Dermal Technical Working Group (10/24/06).
- Completing Histopathology for BCOP tested materials (12/06).
- Submission of BRD to ICCVAM (Spring ’07).
- Brief PPDC on preliminary ICCVAM reaction (May ’07).
- EPA consideration of Interim Science Policy for non-animal assays (Summer/Fall ’07).

5 – Year Plan for Alternative Methods

Congress has requested that the ICCVAM, in partnership with relevant federal agencies, develop a 5-year plan that addresses research, development, translation and validation of new and revised non-animal and other alternative assays for integration into federal agency testing programs, identification of areas of high priority for new and revised non-animal and alternative assays for replacement, reduction, and refinement (less pain and distress) of animals tests.

5 – Year Plan for Alternative Methods

- The EPA priorities will be organized by OSCP
- NIEHS will organize agencies' priorities
- The process to develop the 5-Year Plan includes opportunities for public comment on the criteria for selection and the draft priority list