Panel Discussion: Common Pitfalls in Submissions

Brian Belliveau, Ph.D.
Microbial Unit, Health Evaluation Division, PMRA
November 13-15, 2001
Marriott Crystal Gateway
Arlington, VA
Labelling Issues

- Standard statements not followed as per Registration Handbook and/or Guidelines (microbials), e.g., disposal for TGAI, MP, EP
- Always require “POTENTIAL SENSITIZER” and “CAUTION - EYE IRRITANT” (if no eye irritation study submitted) on principal display panel (microbials)
Labelling Issues

- Include date of manufacture and expiry statement (microbials) on principal display panel
- Product name and guarantee on label does not match PSF (TGAIIs and EPs)
- Strain designation not included in Guarantee line of TGAI, EP labels (microbials)
Product Specification Form (PSF)  
Issues

◆ Each ingredient must be listed on % w/w basis
◆ Nominal concentrations for each ingredient preferred (with upper and lower limits)
◆ All ingredients must total 100%
◆ Include CAS#s for formulants
◆ Print legibly if not submitting electronic form
Data Issues

- Rationales for data omission (waiver requests) missing or not based on sound scientific reasoning
- Waivers not supported by literature on related species/strains/isolates or results of literature search (key search words, data bases), if no papers published
- Papers not accompanied by a critical review demonstrating how each addresses underlying concern behind requirement
Data Issues

- QA/QC data lacking for microbial products, including 5 batch analysis for microbial contaminants; must demonstrate absence of primary pathogens
- No/inadequate storage stability studies for microbial products to support storage claims (temperature range and shelf life) on EP label
- MSDSs or manufacturer’s specifications (plus tech. info.) on formulates (e.g., emulsifiers, stabilizers, preservatives) missing
Data Issues

◆ Test substance not clearly identified in study report
◆ Inappropriate test material (PAI, TGAI, EP) and test concentrations selected
◆ Not enough raw data to allow for independent analysis
◆ No request for pre-submission consultation to identify product-specific data requirements