

US EPA ARCHIVE DOCUMENT



PRIA PROCESS IMPROVEMENTS WORK GROUP

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Statutory Provision

- “To the maximum extent practicable consistent with the degrees of risk presented by pesticides and the type of review appropriate to evaluate risks, the Administrator shall identify and evaluate reforms to the pesticide registration process under this Act with the goal of reducing decision review periods in effect on the effective date of the Pesticide Registration Improvement Act of 2003 for pesticide registration actions for covered pesticide registration applications (including reduced risk applications).”

What We've Done To Date

- Learning from other Fee-based Programs
 - U.S. Food and Drug Administration
 - Canada's Pest Management Regulatory Agency
- OPPIN Enhancements
- Study Processing
 - Sped up the 86-5 data review process
- New Application Screening Procedures
 - Daily review of incoming applications
 - Electronic invoicing of registrants
 - Updating interpretations of categories

What We've Done to Date

- Completeness Checks
 - Are all the forms and labels present?
 - Were labels submitted?
- Improved Coordination with IR-4
- Scoping Before Starting Reviews
 - Determine what type of review is needed

PRIA Process Improvement

- FACA Work Group update - Greg Watson
- OPP Label Committee - Elizabeth Leovey
- Public Participation – Lois Rossi
- AD/Industry Process Improvements – Michael Hardy

PRIA Process Improvement FACA Work Group

- Support for FACA remains strong
 - Submission models for AD meant to aid smaller firms, not likely part of industry organizations
- 14 Problem statements provided and prioritized
- High priority, across all Divisions - Labeling

PRIA Process Improvement Labeling

- Label Review Manual needs to be updated
- Issues continue to be identified, provided use patterns where additional guidance suggested
- PR Notice on adult mosquito label language a good start

PRIA Process Improvement

- Emphasis of FACA
 - Labeling
 - Public Participation - provided requested feedback to RD
 - Continue to identify additional areas for improvement
 - Identify means to measure improvement and efficiency

PRIA Process Improvement OPP Label Committee

- Purpose:
 - Address cross-cutting label policy issues
 - Maintain currency of Label Review Manual
 - Manage Web Site/E-mail box devoted to label issues

PRIA Process Improvement OPP Label Committee

- Representatives from AD, BPPD, RD and SRRD
- Support from FEAD, Office of General Counsel, and Office of Enforcement and Compliance Assurance
- Report to Oversight Committee of AD, BPPD, RD, SRRD, and FEAD Division Directors

PRIA Process Improvement OPP Label Committee

- 6 Month Work Plan Proposed
- E-mail box
- Subgroup for Label Review Manual/Website
- Development and Implement process for resolving issues
 - Further prioritize label issues
 - Identify additional issues

PRIA Process Improvements

Registration Division Public Participation Update

AD/Industry Process Improvements Related to PRIA Topics

- Purpose of AD/Industry Meetings
- Industry Perspective on AD PRIA Actions
- AD Perspective on Industry PRIA Actions
- Registration Model
- Next Steps

Process Improvement Meetings

- AD met with Industry representatives to improve the PRIA process
- AD has previous experience dealing with statutory deadlines as a result of FQPA
- Most of the streamlining activities from FQPA are still being utilized under PRIA
- Both AD and Industry sought methods to ensure “good” submissions the first time through

Industry Perspective on AD PRIA Actions

- Industry had a few examples of problems involving AD and PRIA
- Most of the issues were company specific, not “across the board”
- Industry wanted to assist AD with educating small businesses in terms of PRIA

AD Perspective on Industry PRIA Actions

- Applications were not being identified as being subject to PRIA (led to some confusion with FQPA)
- Data submissions continue to be rejected due to format issues
- Too much time being spent on “fixing” submissions
- One-third of applications are deficient
 - No Offer to Pay Statement
 - Incomplete Data Matrix
 - Wrong MRID numbers
 - All acute studies not addressed

Registration Models

- AD and Industry decided to develop examples of registration packages for small businesses to follow
- These Registration Models would range from a Me-Too registration to a New Active Ingredient registration
- These Models would be represent an electronic example of what the package should look like
- Registration Models will include a submission checklist

Submission Checklist (Fast Track)

- EPA SUBMISSION CHECKLISTS
- Me-Too End-Use Product / Identical or Substantially Similar / With Product-Specific Efficacy and Product Chemistry Data
- Administrative Material (NOT BOUND)
- 1 original cover letter:
- 1 copy of cover letter per study set (1 copy to go with each)
- 1 copy of transmittal document/bibliography with cover letter
- 1 copy of transmittal document per study set (1 copy to go with each)
- 3 copies of EPA Form 8570-1 Application for Pesticide Registration
- 3 copies of EPA Form 8570-4 Confidential Statement of Formula
- 1 copy of EPA Form 8570-27 Formulator's Exemption Statement
- 1 copy of EPA Form 8570-34 Certification with Respect to Citation of Data
- 1 copy of EPA Form 8570-35 Data Matrix, selective method
- 1 copy of EPA Form 8570-36 Summary of the Physical/Chemical Properties, if applicable

Submission Checklist (Fast Track cont'd)

- 1 copy of EPA Form 8570-37 Self-Certification Statement for Physical/Chemical Properties, if applicable
- 3 copies of Proposed Labeling
- 1 copy of Permission Letter for cited data, if any
- Product Properties Studies (BOUND)
- 1 copy of transmittal document/bibliography loose in front of first bound volume of studies
- 1 copy of cover letter per study set
- 3 copies of product properties studies:
 - OPPTS Series 830, Group A
 - OPPTS Series 830, Group B
 - Efficacy Studies (Bound)
- 1 copy of transmittal document/bibliography loose in front of first bound volume of studies
- 1 copy of cover letter per study set
- 3 copies of efficacy studies

AD/Industry Process Improvements Next Steps...

- AD and Industry will work together in addressing other registration models
- AD and Industry will populate the registration models with data for future posting on the Internet
- AD and Industry will present additional registration guidance at the Workshop later this year