PROTECTING THE ACRE
GROWING THE OPPORTUNITY

ADVANCING EPA EFFICIENCY:

Addressing Backlogs & PRIA VI Priorities

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HARNESSING THE STORM. 2026 ADJUVANTS, INERTS & CROP PROTECTION CONFERENCE

Kudos to the EPA Working Group

Ray McAllister, CPDA
Alexis Bromley, Nutrien
Nandi Nagaraj, UPL
Melinda McCann, Drexel
Nathan Ehresman, Albaugh
Karen Warkentien, AgroSpheres
Matt Wilfong, Atticus
Terry Kippley, CPDA
+ Online Participants

12/1/25 OPP RD Leadership Meeting

Why We Matter

“CPDA EPA Working Group provides facetime with EPA. We can provide input into policy decisions that impact our industry. What is successful, is EPA seeing we are an aligned industry.” ~Melinda McCann, Drexel

“CPDA EPA Working Group is invaluable, as it enables direct engagement with industry leaders and fosters alignment around shared regulatory priorities, allowing the industry to engage EPA with a coordinated, informed, and unified voice. CPDA’s focused, technical scope enables efficient working level engagement with EPA, thereby driving actionable regulatory outcomes.” ~Kevin Dearwester, Helm

“CPDA has become The Trade Group to support generic registrants’ regulatory initiatives and take generic registrant issues straight to the EPA OPP administrators. The initiative to reduce the PRIA backlog stands out as one of the biggest successes of the EPA Working Group.” ~Crystal Layton, Rainbow

RD Process Improvements

CITAB EFFICIENCES

- Revise workstream/process for Non-PRIA actions and for resubmissions after 75-day letters

LABEL REVIEW

- Develop external label review challenges and guidance document
- Revisit partial label amendment review process

DEVELOP EXTERNAL COMMUNICATION ON OMRI CLAIMS

CREATE INTERNAL BEST PRACTICES ON TRACKING WHEN RD IS WAITING ON REGISTRANT RESPONSES

PRIA VI Priorities
Discussion Items

- Separate category for 100% Repack Only.
  - Simple, on-time decisions (timeline and cost tbd)
  - Letter of Supply; Letter of Authorization for Data result in expedited decisions
- Reduce PRIA categories overall - misinterpreted / unused categories.
- Subregistrations – same day confirmation (Not a PRIA Action).
- Use Front-End Screen to prevent “bad submissions” from clogging review process.
- Clarification to Primary and Secondary categories
- Funding clauses for update / maintenance of Inert Finder

PRIA Code Consolidation – R Codes

Major Code Reductions (~50%+)

- New Products: 18 → 7
- New Uses: 23 → 11
- New Actives: 13 → 6
- Tolerances: 13 → 5

Simplified Structures

- New Actives: Single code; "Reduced risk" handled via workflow logic
- New Uses & Tolerances: Base code + multiplier approach, fee caps retained
- New Products: One base code (covers up to 2 actives / 3 pests) + add-on fees

Safeners Treatment

- EPA supports aligning safeners with new actives for timelines/fees
- Regulatory review still distinguishes safeners

Operational Streamlining

- Problematic codes consolidated (e.g., R333, R334)
- 100% repack codes retained for automation
- Front-end workflow (MyPest) critical for correct routing

Transition Planning

- Mapping from PRIA 5 → PRIA 6 via internal systems
- "Cheat sheet" crosswalk to aid stakeholders

Next Steps

- Develop interpretations & definitions early
- Possible further reductions in amendment codes
- Consensus reached: structure aligned, ready to proceed to refinements

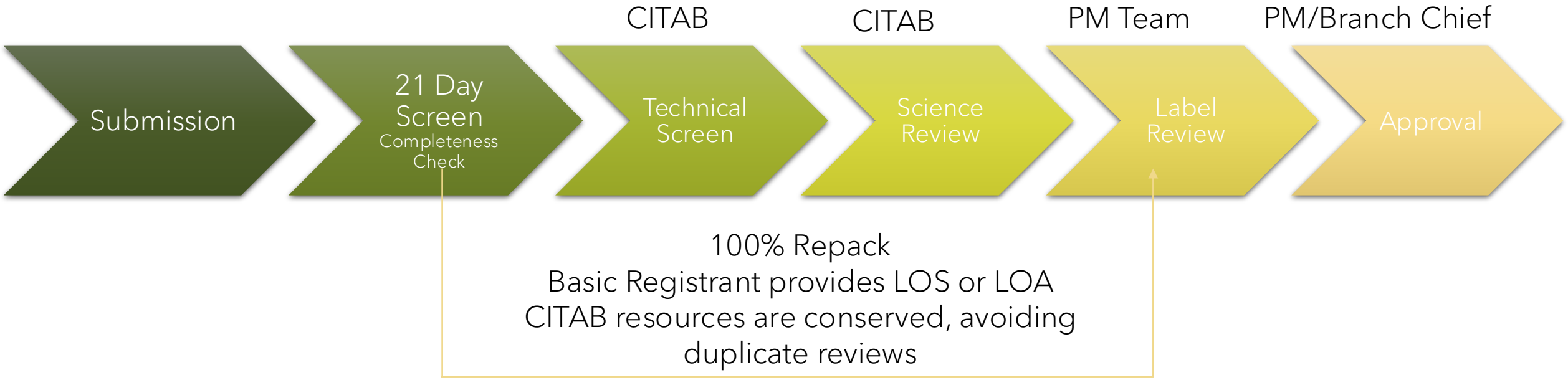
(Source: PRIA 6 – R Codes Meeting, April 9, 2026)

Process Efficiency Proposals for Post-Patent Products Messaging

Proposals

- 100% repacks receive expedited reviews with minimal label amendments
- Cite-All under Selective Citation is blanket coverage for fulfilling guideline requirements
- Resources dedicated to just “Me-Too” decisions
  - Dedicated Teams – Training Opportunities

Process Efficiency Proposals for Post-Patent Products Current Review Process & Proposed Improvements



PRIA 6 Proposal for Me-Too End Use and MUP product categories in Registration Division.

Category	Description	Conditions / Requirements	PRIA Timeline (months)	Cost
Me-Too, Identical (Verified Source) (Ryyy) • Me-Too End Use or Manufacturing Use Product. • No Data Review required, with Verified Source.	•New registration, based only on previously approved registration. •Proof of support from cited Me-Too Registrant. •No CITAB resources for either Scenario 1 or 2	Scenario 1: Submission of 100% repack application with Letter of Supply (Support) from Registrant whose product is being repacked. Scenario 2: Submission of Live CSF, identical to that of cited me-too product, with Letter of Authorization from cited Registrant to cite previously reviewed (and approved) Product Chemistry / Toxicology studies.	1	$3,000

Contextual explanations and rationale for proposal

Expedited Me-Too End Use or MUP Product Review (Ryyy)

•Scenario 1: Submission of a 100% repack with a Letter of Supply (Support) from the Registrant whose product is being repacked. Registration is based on permission-granted Formulator's Exemption. There is no data review required, as the basis of the new registration is the data previously approved for the repacked product's registration.

- Label: review required only to verify the same (or fewer) uses and same restrictions as cited product. Statements in the application cover letter and on Form 8570-1 could identify the specific label (by approval date in PPLS) of the cited product upon which the new product application is based.
- Multiple source products cited in one application, each with its own Letter of Supply, may necessitate a fee multiplier, while retaining the same timeline.

•Scenario 2: Product submission with a Live CSF detailing a composition identical to previously approved product including only the same registered tgai sources. A Letter of Authorization from the cited Me-Too product's Registrant allows citation of previously reviewed data. Requirements are fulfilled as follows:

- Composition: CSF of submitted product to be identical to cited Me-Too product.
- Product Chemistry Data: Letter of Authorization for previously reviewed and approved studies.
- Toxicology Data: Letter of Authorization of previously reviewed and approved studies OR Data Matrix citation same as Me-Too product.
- Technical Data: Formulator's Exemption in same manner as cited Me-Too Product.
- Label: review required only to verify the same (or fewer) uses and same restrictions as cited product. Statements in the application cover letter and on Form 8570-1 must identify the specific label (by approval date in PPLS) of the cited product upon which the new product application is based.
- Multiple source products cited in one application, each with its own identical live CSF and Letter of Authorization, may necessitate a fee multiplier, while retaining the same timeline.

THANK YOU