

PRIA 3 Quarterly Stakeholder Meeting

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U.S. Environmental Protection Agency

Office of Chemical Safety and Pollution Prevention

Office of Pesticide Programs

July 11, 2018

AGENDA

- Introductions
- PRIA 4 Update
- Follow-up from previous Stakeholder Quarterly Meeting
- PRIA 3 Summary for FY'18 through June 2018
- Renegotiation rates: FY'18 through June 2018
- On-time completion rates FY'18 through June 2018
- Pending Non-PRIA Fast Tracks & Notifications through June 2018
- Fees collected: FY'18 through July 5, 2018
- 2-day label approval: FY'18 through June 2018
- Electronic label reviews: FY'18 through June 2018
- Electronic Submissions: FY'18 through June 2018
- 45/90 Preliminary technical screen: FY'18 through June 2018
- Next Meeting Date
- Stakeholder issues



PRIA 4 Update

- An amendment to H.R. 1029 passed in the Senate on June 28, 2018;
- The amendment reauthorizes PRIA for 5 years, starting October 1, 2018, and running through September 30, 2023;
- The amended bill now goes back to the House of Representatives to be reconciled with the original bill passed on March 20, 2017.



Previous Stakeholder Meeting Follow-up – CATSAC

- Standard Evaluation Procedure (SEP) development continues;
 - purpose is to give guidance on both product chemistry and acute toxicity evaluation process;
 - provide common definitions and terminology such as 100% repack, identical products, substantially similar products, and potential for bridging data;
- Proposed PRIA 4 Category;
 - MO10 211: Conditional ruling on pre-application, product substantial similarity, 4 months, \$2,363

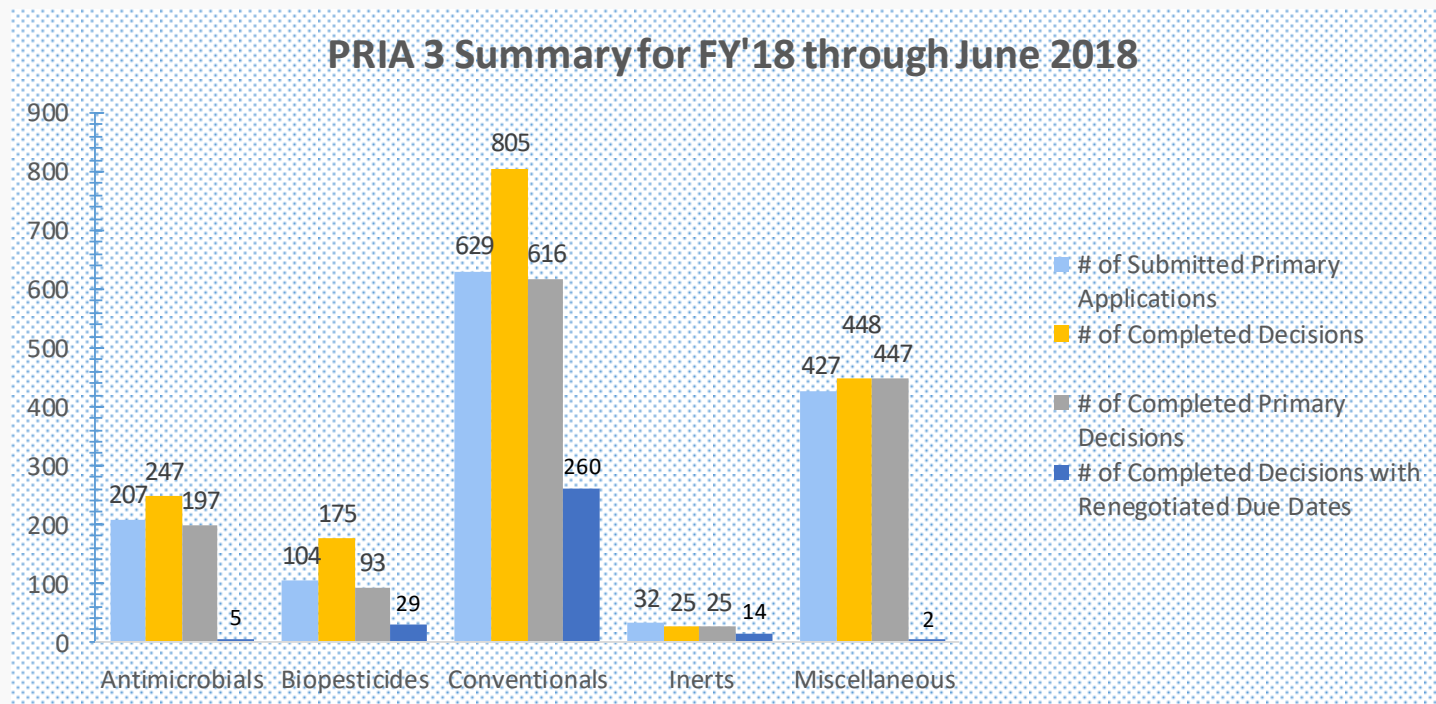


Previous Stakeholder Meeting Follow-up (cont'd) – Notifications PR Notice

- Status of Updated PRN on Notifications
 - Announcement of Updated PRN comments received and being reviewed by EPA
 - Range of comments include:
 - Objection to elimination of ability to add via notification
 - Additional sources of a.i.
 - Suppliers of inert ingredients
 - Changes to inert ingredient nominal concentration, certified limits
 - Inert ingredient disclosure statement
 - Fragrances/dyes
 - Terminology clarifications (e.g., public health pest)
 - Symbols, logos, graphics;
 - EPA is developing its response to comments.



FY'18 PRIA Submissions, Completions, and Renegotiations





Historical % of Completed PRIA Decisions with Renegotiated Due Dates

FY	Antimicrobials	Biopesticides	Conventionals	Misc.	Inerts
2010	108/310 = 34.8%	85/138 = 61.6%	277/1069 = 25.9%		
2011	85/346 = 24.6%	48/134 = 35.8%	236/1074 = 22.0%		
2012	86/333 = 25.8%	74/133 = 42.8%	235/1068 = 22.0%		
2013	73/329 = 22.2%	34/111 = 30.6%	205/1039 = 19.7%	0/562 = 0%	1/7 = 14.3%
2014	41/287 = 14.3%	30/129 = 23.2%	259/895 = 28.9%	1/575 = 0.2%	9/45 = 20%
2015	44/319 = 13.8%	28/154 = 18.2%	229/960 = 23.8%	2/622 = 0.3%	18/56 = 32.1%
2016	31/350 = 8.9%	22/151 = 14.6%	254/977 = 26.0%	2/643 = 0.3%	21/49 = 42.9%
2017	26/338 = 7.7%	22/163 = 13.5%	197/937 = 21.0%	0/544 = 0%	16/42 = 38.1%
2018 thru 6/18	5/247 = 2.2%	29/175 = 16.6%	260/805 = 32.3%	2/448 = 0.4%	14/25 = 56%



FY'18: On-Time Completion Rates

Type of decision	FY'18 Late Completions (through June)	FY'18 Rate of on-time Completions (through June)	FY'17 Rate of on-time Completions	FY'16 Rate of on-time Completions	FY'15 Rate of on-time Completions
Antimicrobial	1	99.6%	99.7%	99.4%	96%
Biopesticide	0	100%	98.8%	97.4%	98%
Conventional	3	99.6%	98.7%	98.6%	99%
Inert	0	100%	95.2%	95.9%	96%
Misc	1	99.8%	99.8%	99.8%	99%
Total	5	99.7%	99.1%	98.9%	98%



FY'18 Non-PRIA Fast-Track Amendments & Notifications

- Through June, 2018, AD completed 462 non-PRIA fast track amendments and has 250 non-PRIA fast-track amendments pending, 112 of which are in backlog status (pending > 90 days). AD completed 842 notifications through June; 291 are pending, of which 251 are in backlog status (pending > 30 days);
- Through June, 2018, BPPD completed 151 non-PRIA fast track amendments and has 111 non-PRIA fast-track amendments pending, 70 of which are in backlog status. BPPD completed 163 notifications through June; 86 are pending, of which 74 are in backlog status;
- Through June, 2018, RD completed 839 non-PRIA fast track amendments and has 811 non-PRIA fast-track amendments pending, 622 of which are in backlog status. RD completed 814 notifications through June; 352 are pending, of which 298 are in backlog status.



Fees Collected in FY18 through July 5, 2018



PRIA Fees: \$12.7M

Maintenance Fees: \$28.2M



FY'18 Through June 2018: Two-Day Label Review Approval Tracking Report Summary

Table 1: Completed Decisions Resulting in New or Amended Product Label Approvals

	Antimicrobial Decisions (A)	Conventional Decisions (R & M005)	Total
Completed Decisions	247	810	1,057
Completed PRIA 3 Decisions	245	808	1,053
PRIA 3 Decisions Involving Label Approvals	234	680	914

Table 2: Timing for Completion of PRIA 3 Label Reviews & Approvals

	Antimicrobial Label Reviews & Approvals (A)	Conventional Label Reviews & Approvals (R & M005)	Total
After the PRIA Due Date	1 (<1%)	2 (<1%)	3 (<1%)
On the PRIA Due Date	80 (34%)	135 (20%)	215 (24%)
Before the PRIA Due Date but after the Pre-decisional Determination due date	107 (46%)	344 (51%)	451 (49%)
On or before the Pre-decisional Determination Due Date	46 (20%)	199 (29%)	245 (27%)
Total	234	680	914



FY'18 through June 2018: Electronic Label Reviews

- Tracking the use of electronic comparison software in conducting label reviews requires input from reviewers;
- Lack of necessary input increases uncertainty;
- % of labels reviewed electronically in RD: 87% - 92%;
- % of labels reviewed electronically in AD: 90% - 95%;
- % of labels reviewed electronically in BPPD: 58% - 89%.



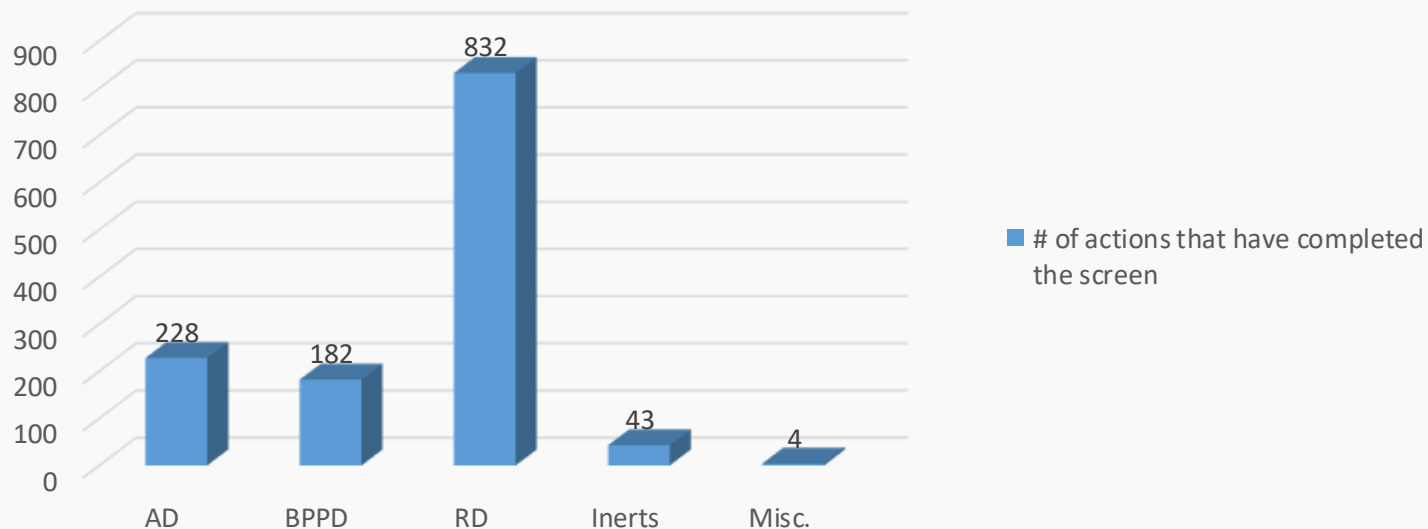
FY'18 through June 2018: All Stakeholder Registration Submissions by Type of Product

Type of Product	Total # of Submissions	# Paper Submissions	# CD/DVD Submissions	# of Portal Submissions	% Paper Submission	% CD/DVD Submission	% Portal Submission
Conventional	5,653	2,975	10	2,668	53%	<1%	47%
Antimicrobial	1,861	580	4	1,277	31%	<1%	69%
Biopesticide	832	357	37	438	43%	4%	53%
total	8,345	3,911	51	4,383	47%	<1%	53%



FY'18 through June 2018: 45/90-day Preliminary Technical Screen

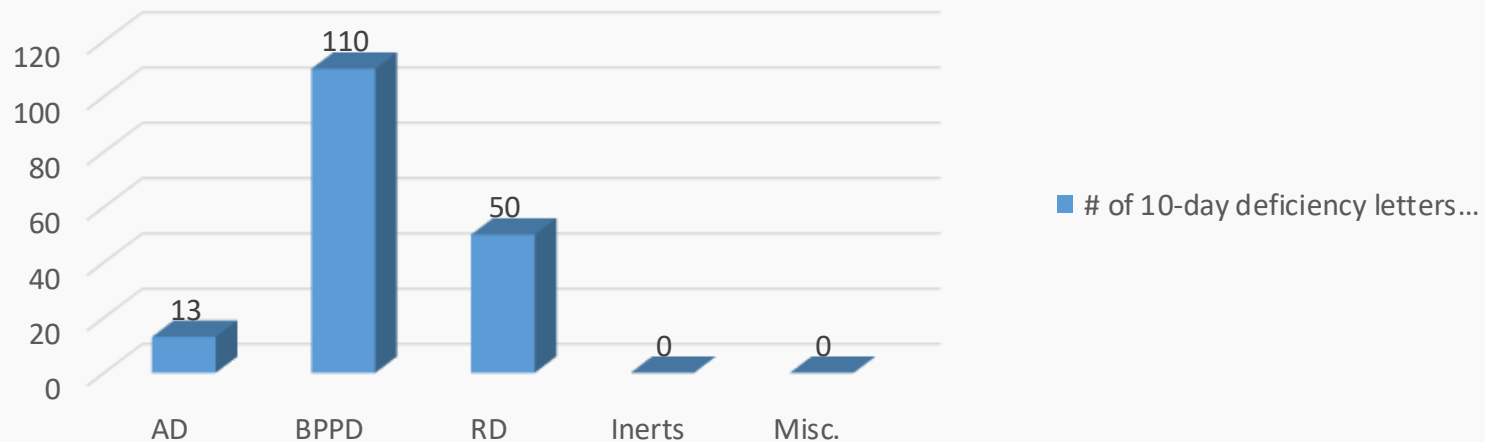
Actions That Have Completed the Screen





FY'18 through June 2018: 45/90-day Preliminary Technical Screen (*cont'd*)

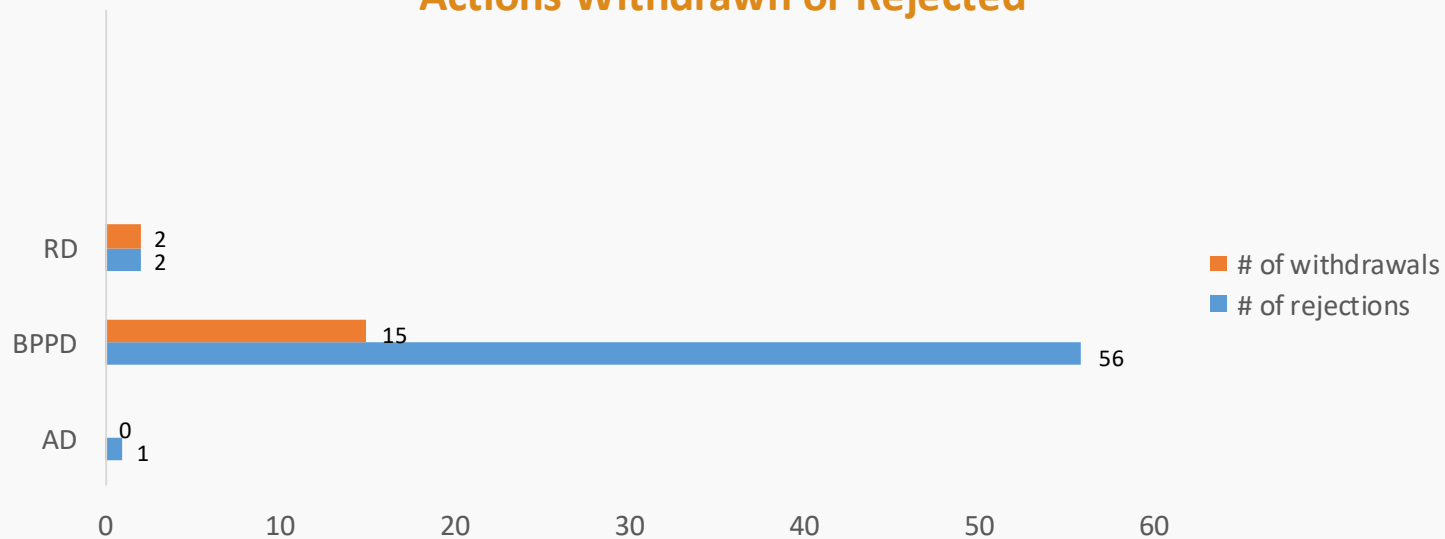
10-day Deficiency Letters Sent Out





FY'18 through June 2018: 45/90-day Preliminary Technical Screen (cont'd)

Actions Withdrawn or Rejected





FY'18 through June 2018 : Reasons for 45/90 Screen Rejections/Withdrawals

- Data deficiencies/ Missing data, rationale, or waiver request
- Uncleared inerts/ missing inert data
- Inert ingredient misidentified
- Data matrix/data compensation issues
- Not substantially similar (both label and formulation)
- Inadequate efficacy data to support claims
- Citing studies relating to a different a.i.
- Bridging argument unacceptable



Future PRIA Stakeholder Meeting Date

- Wednesday, November 14, 2018
- Meeting will be held on the 1st floor conference room from 1:00PM – 4:00PM



Stakeholder Issues

- Questions?
- Potential topics for the next meeting



PRIA Points of Contact

- Steve Schaible, Senior Advisor, PRIA Coordinator:
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