PRIA 3 Quarterly Stakeholder Meeting

AGENDA

December 16, 2014

- Introductions
- Budget Resource Update
- PRIA 3 Summary for FY'14 (October 1, 2013 – September 30, 2014)
- 45/90 Preliminary Technical Screen
- Fast Track Amendment & Notification Backlogs
- Lean Projects
- Update on OPP Electronic Portal Development
- Label activities update

PRIA 3 Summary for FY'14 (October 1, 2013 – September 30, 2014)

- Number of application submissions – October 1, 2013 thru September 30, 2014
    - Antimicrobials – 317
    - Biopesticides – 162
    - Conventionals – 1,052
    - Inerts – 64
    - Miscellaneous – 554 (541 were gold seal letter requests)
    - Total – 2,149

- Number of completed decisions – October 1, 2013 thru September 30, 2014
    - Antimicrobials – 287 (256 primary decisions)
    - Biopesticides – 129 (106 primary decisions)
    - Conventionals – 895 (678 primary decisions)
    - Inerts – 45 (27 food-use inerts cleared; 18 non-food use inerts cleared)
    - Miscellaneous – 575 (570 gold seal letters)
    - Total – 1,931 (1,660 primary decisions)

- Number of completed decisions with renegotiated due dates – October 1, 2013 thru September 30, 2014
    - Antimicrobials – 41 (14.3%)
    - Biopesticides – 30 (23.2%)
    - Conventionals – 259 (28.9%)
    - Inerts – 9 (20%)
    - Miscellaneous – 1 (0.002%)
    - Total – 340 (17.6%)

- Historical **%** of completed PRIA decisions with renegotiated due dates

FY	Antimicrobials	Biopesticides	Conventionals	Misc.	Inerts
2009	68/342 = 19.9%	42/124 = 33.9%	193/1104 = 17.5%		
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 = 0.002%	9/45 = 20%

*To deal with the backlog which resulted from the government shutdown, OPP eschewed renegotiating due dates in favor of utilizing that time and resources to reduce the backlog. This has been referred to as "the short-term strategy". This strategy was in place from the middle of October 2013 to the middle of January 2014. Consequently, FY'14 renegotiation percentages are somewhat of a special case.

- Number *of* PRIA decisions completed late – October 1, 2013 thru September 30, 2014
    - Antimicrobials – 63
    - Biopesticides – 27
    - Conventionals – 193
    - Inerts – 4
    - Total – 292 (translates into a 85% on-time completion rate)

- 2-day Label Review Status

2-Day Label Approval Tracking Report - Summary

Division(s): All
Completion Date: 10/1/2013 to 9/30/2014

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

	Antimicrobial Decisions (A)	Conventional Decisions (R & M005)	Total
Completed Decisions	287	897	**1,184**
Completed PRIA 3 Decisions	272	758	**1,030**
PRIA 3 Decisions Involving Label Approvals	259	593	**852**

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	50 (19%)	56 (9%)	**106 (12%)**
On the PRIA Due Date	65 (25%)	71 (12%)	**136 (16%)**
Before the PRIA Due Date; Pre-decisional Determination Due Date is null	1 (<1%)	0 (%)	**1 (<1%)**
Before the PRIA Due Date but after the Pre-decisional Determination due date	96 (37%)	239 (40%)	**335 (39%)**
On or before the Pre-decisional Determination Due Date	47 (18%)	227 (38%)	**274 (32%)**
Total	**259**	**593**	**852**

- Net amount of PRIA fees collected in FY'14 -- $16,611,313
- Amount of maintenance fees collected in FY'14 -- $28,656,000

45/90 Preliminary Technical Screen – October 1, 2013 thru September 30, 2014

- # of actions that have completed the screen – 1,600
    - AD – 283
    - BPPD – 155
    - RD – 1,162
- # of 10-day deficiency letters sent out – 149
    - AD – 41
    - BPPD – 34
    - RD –74
- # of rejections/# of withdrawals – 8/41
    - AD – 5/10
    - BPPD – 1/12
    - RD – 2/19
- Reasons for rejections/withdrawals
    - Not substantially similar
    - Missing data
    - Data deficiencies
    - Uncleared inerts
    - Inadequate characterization of strain
    - Inadequate acute toxicity data
    - Waiver request for post-application exposure study denied
    - Data matrix/data comp issues

Fast Track Amendment & Notification Backlogs (as of September 30, 2014

- AD had 91 fast track amendments pending, and 14 were in backlog status (i.e. more than 90 days have elapsed);
- AD had 24 notifications pending, and 10 were in backlog status (i.e. more than 30 days have elapsed);
- BPPD had 31 fast track amendments pending, and 21 were in backlog status;
- BPPD had 25 notifications pending, and 18 were in backlog status;
- RD had 258 fast track amendments pending, and 47 were in backlog status;
- RD had 122 notifications pending, and 67 were in backlog status

Lean Activities (Process Improvements)

Over the past few years EPA and state environmental agencies have experimented with using Lean to improve government processes. Lean is a collection of principles, methods, and tools that improve the speed and efficiency of any process by eliminating waste. Although Lean originated in manufacturing operations, the tools have been successfully applied in organizations across all sectors, including the government.

OPP has employed this continuous improvement approach to improve some of our business processes, making them more efficient and consistent across the program. OPP has conducted Lean workshops for 6 processes. These Lean workshops were comprised of multidivisional teams and resulted in some immediate and short-term implementations. These implementation plans better utilize existing tools and resources, and get rid of unnecessary steps to allow us to more efficiently produce high-quality work.

1) Label review, approval, and posting process
    a. Reduced time from label approval to posting from 16 to 3 days on average by implementing electronic signatures, stamps and automated PPLS uploads across regulatory divisions
    b. Improved quality of labels posted to PPLS (fully searchable, color documents)
    c. Increase consistency of label approval letters by standardizing templates across regulatory divisions
2) Federal Register publication process for NOIs, NORs, and NOFs
    a. Reach a broader audience by publishing NOIs to OPP website similar to Section 18s
    b. Increase number of polymer NOFs published on time by modifying FR batching process
    c. Reduce number of review cycles by revising FR review process
    d. Increase quality of notifications by formalizing process for updating FR templates
3) Front-end process
    a. Outreach and training to increase number of electronic submissions
    b. Cataloguing errors with current electronic submission to inform future improvements
4) Creation, maintenance, storage, and retrieval process for jackets
    a. Reduce growth of paper jackets by eliminating redundant, unneeded documents from regulatory record
    b. Increase centralized storage of fully searchable electronic documents to create an electronic regulatory record
5) Optimizing chemical team interactions
    a. Streamline & accelerate registration review process for conventional chemicals
    b. Provide earlier opportunity for registrant to weigh-in on uses being assessed
    c. Increase consistency of review process between chemicals to provide more level playing field
    d. Earlier publishing of preliminary risk assessment when additional data are not needed
    e. Capture reg review decisions in a database to inform decisions on similar chemicals
6) Risk assessment groundwork process
    a. Reduce time spent by assessors collecting information by consolidating and optimizing internal information systems
    b. Consolidate internal workload tracking systems across divisions

Update of OPP Portal Development

[PowerPoint presentation]

OPP Portal Development

PRIA Stakeholder Meeting
December 2014

Portal Concept

- Portal is a secure submission route for pesticide application package
- Electronic files and corresponding metadata are securely delivered to OPP information systems
- Authentication – Requires establishing an account based on necessary info (company info, etc.) prior to use of portal

Portal Development Team

- OPP-wide team comprised of business users & IT experts ensure portal development meets OPP's needs and fits in with the larger IT vision for OPP
- Obtained input from other Agencies on their experience with electronic submission and any lessons learned
  - FDA
  - Cal DPR
  - PMRA
  - US Patent and Trademark

Feedback from Other Agencies

- Make electronic submission via the portal as simple as possible initially
- Encourage adoption of electronic submission by
  - Balancing ease of use with goal of high quality submissions
  - Outreach to external stakeholders
- Give careful consideration to where validation is performed
  - Validation can occur before and after packages are submitted through the portal
- Replacing of paper with electronic documents – seemingly small step – is hugely beneficial

Portal Development Objectives

- Stage portal development for electronic submission
  - Replace paper with electronic documents
  - Replace unstructured information with structured information
  - Align structured information with OPP information systems
- Balance validation needs of receiver (OPP staff) with burden on submitters (registrants)
- Outreach to external users
  - Receive feedback on portal interface
  - Provide training and support tools

Portal Development Phases

- Initial development phase
  - Establish secure portal
  - Upload submission package from current e-dossier builder
  - Include metadata & validation currently available for e-submissions
- Later development phases
  - Expand upload functionality (Smart Labels, studies, supporting docs, etc.)
  - Develop validation rules to improved submission quality
  - Incorporate additional builder tools (e-CSPS builder)

Electronic Submission with CD Builder

Electronic Submission with Portal

Benefits of Electronic Submissions

- Better quality submission packages
  - Ensure submission package contains program-specific information requirements (e.g., PRIA codes)
  - Productivity increase via automation
- Allows improvement to electronic workflow
  - More efficiently move packages to next in line