PRIA 3 Quarterly Stakeholder Meeting

AGENDA

March 20, 2014

- **Introductions**
- **Status on Implementing Other IT Set-asides**
- **Status on Implementing Automated Registration Email Milestone Tracking System**
- **Status on Implementing Conditional Registration Tracking System**
- **Demo of New PRIA External Web page Format**
- **PRIA 3 Summary for FY'14 (October 1, 2013 to March 1, 2014)**
- **Status of Short-term Strategy to Deal with Shutdown-induced PRIA Backlog**
- **45/90 Preliminary Technical Screen Summary**
- **Status of PR Notice on the Economic Definition of a Minor Use**
- **Budget/Resources Update**

Budget/Resource Update

(see handout

Quarterly PRIA 3 Report -- March 20, 2014

PRIA 3 Status: October 1, 2013 – March 1, 2014

- Number of application submissions since Oct. 1, 2013 -- March 1, 2014
    - Antimicrobials – 103
    - Biopesticides – 44
    - Conventionals – 260
    - Inerts – 21 [11 food use; 10 non-food use]
    - Miscellaneous – 201 [197 are Gold Seal letter requests]
    - Total -- 629

- Number of completed decisions since Oct. 1, 2013 -- March 1, 2014
    - Antimicrobials – 102 (93 primary decisions)
    - Biopesticides – 55 (48 primary decisions)
    - Conventionals – 387 (264 primary decisions)
    - Inerts – 21 [16 food use inerts cleared; 5 non-food use inerts cleared]
    - Miscellaneous – 199 [198 are Gold Seal Letters]
    - Total -- 764 (625 primary decisions)

- Number of completed decisions with due date extensions since Oct. 1, 2013 – March 1, 2014
    - Antimicrobials – 24 (23.5%)
    - Biopesticides – 10 (18.2%)
    - Conventionals – 113 (29.2%)
    - Inerts – 3 (14.3%)
    - Miscellaneous – 0
    - Total -- 150 (19.6%)

% of completed PRIA decisions with due date extensions

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 to 3/1/14	24/102 = 23.5%	10/55 = 18.2%	113/387 = 29.2%	0/199 = 0%	3/21 = 14.3%

- Amount of PRIA net fees collected (Oct. 1, 2013 to March 1, 2014) -- $7.635M
- Amount of maintenance fees collected in FY'14 to March 1, 2014 – $27.653M

Status of short term strategy to deal with PRIA backlog due to government shutdown

- Government shutdown's impact on PRIA actions more difficult to discern as distance in time from the end of the shutdown increases;

- Status of targeted PRIA actions with Due Dates between Oct. 1, 2013 and Dec. 31, 2013

Type of Action	# of Decisions	# of Completed Decisions (as of March 1, 2014)	Decisions still Pending
AD	77	76	1 (new prod)
BPPD	42	34	5 (2 new AIs), 2 (1 new use), 1 (new prod)
RD	314	287	4 (2 new AIs), 18 (3 new use AIs), 5 (other)
Inerts	11	11	0
Misc	130	130	0
Totals	574	538 (94%)	36

- After January 15th all potentially late PRIA actions needed to renegotiate their due dates;
- 223 PRIA decisions completed late
  - AD – 52
  - BPPD – 19
  - RD – 149
  - I = 3
- Short-term strategy has resulted in:
  - 94% of targeted actions completed;
  - Significant increase in the # of actions completed late;
  - Increases in the percentage of negotiated due dates

Status on implementing automated registration email tracking system

- Seven milestones:
  1. Application receipt date; receipt number assigned
  2. PRIA category(ies) assigned; waiver decision, if applicable, completed; payment completed; 21-day screen timeframe expired; PRIA start date; PRIA due date; pre-decisional determination due date, if applicable;
  3. Contact information for PM assigned to your application; date data sent into review;
  4. 45/90 technical screen timeframe expired;
  5. Actual last science review completion date;
  6. Pre-decisional determination date reached, if applicable
  7. Regulatory decision completed

- Automated emails sent out at each milestone beginning with submissions received after January 1, 2014;
- Registrant must supply an email address for each application to receive email tracking milestones;
- Will not replace current registrant-PM communications;
- "Bundling" capability being pushed into production at this time; Bundling will aggregate into a single email (per milestone) information on related decisions. i.e. a new active ingredient and multiple end use products
- Next step is to work with a stakeholder workgroup to identify desired phase 2 system characteristics.

Status on Implementing Conditional Registration Tracking System

- OPP has already implemented more specific definitions within the list of allowable options available to staff in its OPPIN tracking system that more accurately describe the legal authority under which a conditional registration determination can be made. All OPP staff have been trained in the appropriate use of these new options by OGC and IT staff;
- OPP has reviewed existing conditional registrations for new AIs to confirm receipt and review of required data and compiled information into a consolidated spreadsheet, which includes the following:
    - All new AIs conditionally registered since October 1, 1999 included in review,
    - Lists by each AI all data required as condition of registration,
    - Identifies when the data were due,
    - Identifies when data were received, and
    - Identifies the status of agency's review of these studies.
- The consolidated spreadsheet will be placed on OPP's web once the last entries are complete which is expected by April 15th;
- The consolidated spreadsheet will be used to monitor the timely submission of data;
- OPP management is discussing the best approach to further conditional registration tracking in phase two:
    - Either upgrade existing OPPIN tracking system to automate the tracking of study submission deadlines and internal review due dates for conditionally registered new AIs
    - Or include as required functionality in a to-be-developed tracking system
- Future IT enhancements will address deficiencies identified in the current system and related processes

Status on Implementing Other IT Set-asides

- Electronic labeling (SmartLabel)
    - Vision is to capture label information as structured content and data
    - Assembled an OPP team to discuss options and approach for electronic labeling

- Developing draft XML specification, vocabularies, and validation rules
- Partnering with FDA to leverage their experience with "Structured Product Labeling" (SPL); Pilot planned for summer 2014
- Actively seeking input from stakeholders and regulatory partners

- Electronic Confidential Statement of Formula
  - Developed as an Action Item under the United States – Canada Regulatory Cooperation Council (RCC)
  - EPA and Canada's Pest Management Regulatory Agency (PMRA) identified the need for a consolidated form during 2011 product chemistry workshop
  - Confidential Statement of Product Specifications (CSPS) is a consolidated and harmonized version of EPA's CSF and Canada's specification form
  - Harmonizing will allow applicants to submit a similar form to both agencies with potentially much of the same information and reduce the number of errors
  - EPA conducted an internal pilot using the CSPS paper form and CSFs from products that were nominated by the registrant workgroup
  - EPA began collaborating with the US Food and Drug Administration – similar information is collected on prescription drug formulations
  - Initial briefing of Office of Management and Budget staff occurring shortly
  - Proposing to develop an electronic tool for use in completing the form, allowing the current CSF form to remain in effect while conducting a voluntary pilot of the CSPS electronic tool
  - Use of the electronic tool is anticipated to result in significant time savings and error reduction
  - Preliminary work underway to identify a common IT approach usable by both EPA and PMRA
  - Current plans are to house the electronic tool in a secure web portal accessible to registrants
  - EPA welcomes your input as we move forward on this project

- Endangered Species Assessment Knowledge Database
  - EFED has compiled species-specific body weights, diets, obligate relationships, habitat descriptions and elevation restrictions for currently listed species
  - Enhanced searching and reporting functionalities as well as document storage capabilities have been added

45/90 Preliminary Technical Screen – Summary of FY'14 (Oct 1, 2013 to March 1, 2014)

- # of actions completed screen – 366
  - AD – 99
  - BPPD – 28
  - RD – 228
  - I - 9
  - M - 2

- # of 10-day deficiency letters sent out – 44
  - AD - 11
  - BPPD – 7
  - RD - 26

- # of rejections/# of withdrawals – 4/16
  - AD – 3/4
  - BPPD – 0/6
  - RD – 1/6

Status of PR Notice on Economic Definition of a Minor Use

Determination of Economic Minor Use under FIFRA 2(ll)

- Existing criteria for EMU and reasons for revising
- Applications of minor use status in pesticide policy
- Development of the PR Notice
- Proposed method and criteria for evaluating EMU status