PRIA 3 Quarterly Stakeholder Meeting

Agenda

July 17, 2014

- **Introductions**
- **Budget Resources Update**
- **Issues with incomplete inert submissions**
- **Footnotes in Part 158/protocol reviews**
- **Registration Milestone Email Tracking System**
  - **Issues with email addresses**
  - **Feedback from stakeholders**
- **Fast track amendment backlogs**
- **45/90 Preliminary Technical Screens**
  - **10-day deficiency letters**
  - **# of rejections/withdrawals**
  - **Reasons for rejections**
- **PRIA 3 Summary for FY'14 (October 1, 2013 – July 1, 2014)**
- **SmartLabel Pilot**

Budget Resources Update

Issues with Incomplete PRIA Inert Submissions

- Inappropriate PRIA categories
- Simultaneous submission of registration actions
- Inadequate or missing use information including purpose in formulation
- Inadequate/no justification for analog surrogate data
- Inadequate data and lack of supporting documents
- Inadequate or lack of exposure information

Footnotes in Part 158 regarding Protocol Reviews

- Certain Part 158 data requirements have footnotes that require (or strongly encourage) registrants to submit protocols for approval before initiating the study.
- While PRIA 3 does have PRIA categories for applicant-initiated protocol reviews, the agency has determined that for protocol reviews for the studies listed in the table below, such submissions are not deemed applicant-initiated and no PRIA fee is required.

40 CFR Part 158 Data Requirements that Require/Encourage Protocol Reviews

Guideline #	Study Description	Footnote
835.6200	Aquatic sediment (antimicrobial pesticides) CR	"protocols must be approved by the agency prior to the initiation of the study."
835.6300	Forestry field dissipation CR	
835.7100	GW monitoring CR	
850.1735	Whole sediment acute freshwater invertebrate CR	"Registrants must consult with the Agency on appropriate test protocols prior to designing the study."
850.1740	Whole sediment acute marine invertebrate CR	
	Whole sediment chronic marine & freshwater invertebrate CR	
850.1950	Field test, aquatic organisms (microbial pesticides)	"Since test standards would be developed on a case-by-case basis, consultation with the agency and

Guideline #	Study Description	Footnote
850.2500	Field test, insect predators, birds, mammals (microbial pesticides)	development of a protocol is advised before performing these Tier IV studies."
850.3040	Field test, pollinators (microbial pesticides)	
850.4300	Field test, plants (microbial pesticides)	
850.3030	Toxicity to honeybees (antimicrobial pesticides)	"protocols must be approved by the agency prior to the initiation of the study."
850.4025	Target area phytotoxicity CR	"Registrants must consult with the Agency on appropriate test protocols prior to designing the study."
850.4300	Non-target terrestrial field phytotoxicity CR	
850.4450	Non-target aquatic phytotoxicity CR	
870.3100	90-day oral – rodent R	"The registrant is encouraged to consult with the Agency on results of the 90-day mouse study prior to conducting the carcinogenicity study."
870.4200	Carcinogenicity – 2 rodent species R	
870.3700	Prenatal development (antimicrobial pesticides)	"Applicants must submit any alternative proposed testing protocols and supporting scientific rationale to the agency. Protocols must be approved by the agency prior to initiation of the study."
870.3800	Reproduction and fertility	
870.6300	Developmental Neurotoxicity	
875.1100	Applicator dermal outdoor exposure R	"Protocols must be submitted for approval prior to initiation of the study."
875.1200	Applicator dermal indoor exposure R	
875.1300	Applicator inhalation outdoor exposure R	
875.1400	Applicator inhalation indoor exposure R	
875.1500	Applicator biological monitoring CR	"Protocols must be submitted for approval prior to initiation of the study."
875.2100	Post application dislodgeable foliar residue & turf transferable residues [occupational – R; residential – R]	
875.2200	Post application soil residue dissipation [occupational – R; residential – CR]	
875.2300	Post application indoor surface residue dissipation [occupational – R; residential – R]	
875.2400	Post application dermal exposure [occupational – R; residential – R]	
875.2500	Post application inhalation exposure	"Registrants must consult with the agency on the appropriate study protocol prior to designing the study."
875.2600	Post Application biological monitoring	
875.3000	Post application non-dietary ingestion exposure	

Registration Milestone Email Tracking System

- Lack of clear identification of an applicant's email address in the cover letter has resulted in some incorrect email addresses being entered into the tracking system. Some milestone 1 emails might have gone out to incorrect address.
- Problem was caught at milestone 2 and corrected.
- Need to **CLEARLY IDENTIFY THE EMAIL ADDRESS** you want the milestone tracking to go to.
- General feedback from stakeholders on milestone tracking system thus far

Fast Track Amendment Backlogs (as of July 1,2014)

- AD has 47 fast track amendments & notifications pending and 12 were in backlog status (i.e. more than 90 days have elapsed);
- BPPD has 178 fast track amendments & notifications pending and 171 were in backlog status;
- RD (see handout);

45/90 Preliminary Technical Screens (October 1, 2013 – July 1, 2014)

- # of actions completed screen – 931
  - AD – 195
  - BPPD – 84
  - RD – 652

- # of 10-day deficiency letters sent out – 94
  - AD - 21
  - BPPD – 17
  - RD - 56

- # of rejections/# of withdrawals – 6/31
  - AD – 4/5
  - BPPD – 0/10
  - RD – 2/16

- Reasons for rejection/withdrawal
  - not substantially similar,
  - inadequate acute toxicity data,
  - waiver request for post-application exposure study denied
  - missing data
  - data deficiencies
  - uncleared inerts

- data matrix/data comp issues

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

- Number of application submissions since Oct. 1, 2013 -- July 1, 2014
    - Antimicrobials – 222
    - Biopesticides – 98
    - Conventionals – 545
    - Inerts – 53
    - Miscellaneous – 429 [421 are Gold Seal letter requests]
    - Total -- 1347

- Number of completed decisions since Oct. 1, 2013 -- July 1, 2014
    - Antimicrobials – 216 (192 primary decisions)
    - Biopesticides – 91 (79 primary decisions)
    - Conventionals – 670 (504 primary decisions)
    - Inerts – 34 [19 food use inerts cleared; 15 non-food use inerts cleared]
    - Miscellaneous – 430 [427 are Gold Seal Letters]
    - Total -- 1430 (1228 primary decisions)

- Number of completed decisions with due date extensions since Oct. 1, 2013 – March 1, 2014
    - Antimicrobials – 31 (14.4%)
    - Biopesticides – 18 (19.8%)
    - Conventionals – 205 (30.6%)
    - Inerts – 5 (14.7%)
    - Miscellaneous – 0
    - Total -- 259 (18.1%)

% 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 7/1/14	31/216 = 14.4%	18/91 = 19.8%	205/670 = 30.6%	0/430 = 0%	5/34 = 14.7%

- Amount of PRIA net fees collected (Oct. 1, 2013 to July 1, 2014) -- $14.052M

- Amount of maintenance fees collected in FY'14 to July 1, 2014 – $28.58M

2-Day Label Review Status (October 1, 2013 – July 1, 2014)

Completed Decisions Resulting in New or Amended Product label Approvals

	Antimicrobial Decisions (A)	Conventional Decisions (R & M005)	Total
Completed Decisions	216	672	888
Completed PRIA 3 Decisions	205	544	749
PRIA 3 Decisions Involving Label Approvals	196	428	624

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	47 (24%)	55 (13%)	102 (16%)
On the PRIA Due Date	50 (26%)	49 (11%)	99 (16%)
Before the PRIA Due Date but after the Pre-decisional Determination Due Date	63 (32%)	171 (40%)	234 (38%)
On or before the Pre-decisional Determination Due Date	36 (18%)	153 (36%)	189 (30%)
Total	196	428	624

SmartLabel Pilot Solicitation

Purpose

EPA proposes to pilot the development and submission of pesticide labels as SmartLabels (in xml format) in the fall of 2014. EPA seeks to obtain stakeholder feedback on the draft xml specification, data elements, vocabularies and guidance documentation.

Background

EPA's Office of Pesticide Program seeks to improve pesticide labels, including making the label approval process more efficient and effective. Developing and implementing the SmartLabel, an electronic label in a structured format, will allow pesticide registrants to submit their pesticide label to EPA as structured xml content. The SmartLabel can easily be compared to previous versions of the label, ensuring quicker review times. EPA expects that SmartLabels will be entered into an EPA-developed and maintained database on submission via an electronic "mailbox." The SmartLabel would be processed though validation rules and on approval will be posted to the internet for stakeholders. These electronic processes are expected to improve the timeliness of updated label information being publicly available and will also be more efficient than the comparison of paper and PDF labels that EPA currently uses.

Scope

For the pilot, EPA is soliciting participation from 9 registrants that are willing to develop and submit for testing a number of pesticide product labels (around 10 for each participant) that conform to the SmartLabel specifications. EPA is seeking participation from 3 registrants for each of the following product types for a total of 9 participants:

- conventional pesticides in agricultural products and/or lawn and garden products,
- microbial and biochemical pesticides in agricultural and/or mosquito larvicidal products, or
- antimicrobial pesticides in hospital disinfectant, wood preservative, and/or pool products.

Participation

Participation in the SmartLabel pilot is voluntary. EPA is soliciting participants via the Pesticide Registration Improvement Act (PRIA) Coalition. EPA will provide a training webinar to industry participants to demonstrate methods of creating the SmartLabel (xml format) and to answer questions that participants may have. Participants should be willing to release their pesticide label in the new format, provide feedback on the xml specification, data elements, guidance document and vocabularies. Participants should be willing to identify gaps in the vocabularies and offer alternatives. In addition to the participants, EPA welcomes feedback and comment from all interested parties.

In order to be considered for participation, please contact Marietta Echeverria (echeverria.marietta@epa.gov or 703-305-8578) with the proposed products to be piloted (EPA reg. #) by September 1, 2014.