

Quarterly PRIA 3 Report

June 19, 2013

PRIA 3 Status October 1, 2012 – June 10, 2013

- Number of application submissions since Oct. 1, 2012 -- June 10, 2013
 - Antimicrobials – 187
 - Biopesticides – 70
 - Conventionals – 459
 - Inerts – 24 [23 food use; 1 non-food use]
 - Miscellaneous – 372 [370 are Gold Seal letter requests]
 - Total -- 1,112

- Number of completed decisions since Oct 1, 2012 – June 10, 2013
 - Antimicrobials – 216
 - Biopesticides – 76
 - Conventionals – 764
 - Inerts – 34 [19 food use inerts cleared; 15 non-food use inerts cleared]
 - Miscellaneous – 371 [all Gold Seal Letters]
 - Total -- 1,461

- Number of completed decisions with due date extensions since Oct. 1, 2012 – June 10, 2013
 - Antimicrobials – 53 (24.5%)
 - Biopesticides – 17 (22.4%)
 - Conventionals – 165 (21.6%)
 - Inerts – 1 (2.9%)
 - Miscellaneous – 0
 - Total – 236 (16.2%)

% of completed PRIA decisions with due date extensions

FY	Antimicrobials	Biopesticides	Conventionals
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 ⁱ	53/216 = 24.5%	17/76 = 22.4%	165/764 = 21.6 % ⁱⁱ
2013			165/1135 = 14.5% ⁱⁱⁱ

¹ Includes completed actions from 10/1/2012 through 6/10/2013

² Excludes gold seal letter completions

³ Includes gold seal letter completions

- 45/90 Preliminary Technical Screen
 - # of actions completed screen
 - AD – 175
 - BPPD –46
 - RD – 414
 - Total -- 635
 - # of 10-day deficiency letters sent out – 105
 - # of rejections – 7
 - [6 new products rejected for: not substantially similar, lack of efficacy data to support public health claims, unacceptable bridging argument for multiple AI product; 1 new AI rejected for significant data deficiencies in environmental fate, aquatic eco-tox, residue chemistry & product chemistry];
- Amount of PRIA net fees collected (Oct. 1, 2012 to June 10, 2013) -- \$10.815 M
- Amount of maintenance fees collected in FY 2013 – \$26.929 M
- 2-Day label Review status
 - Purchase and deployment of Comparedocs software
 - Training
 - Experience with use
 - Performance to date: RD
 - 58.3% of RD PRIA 3 completions occurred before Pre-decisional Determination Due Date;
 - 30.7% of RD PRIA 3 completions occurred between Pre-decisional Determination and PRIA Due Dates;
 - 10% of RD PRIA 3 completions occurred on the PRIA Due Date;
 - 1 RD PRIA 3 completion occurred after the PRIA Due Date under the 2-day label review process and was completed in 1 day.
 - Performance to date: AD
 - 32.8% of AD PRIA 3 completions occurred before Pre-decisional Determination Due Date;
 - 53.7% of AD PRIA 3 completions occurred between Pre-decisional Determination and PRIA Due Dates;
 - 13.5% of AD PRIA 3 completions occurred on the PRIA Due Date.