

# Implementing the Pesticide Registration Improvement Act - Fiscal Year 2014

## Eleventh Annual Report



*March 1, 2015*

## **Maintenance Fees**

### **Expedited Processing (FIFRA Section 3(c)(3)(B))**

Under Section 33(k)(2)(A)(iv), the agency is to report the number of applications completed for identical or substantially similar applications under section 3(c)(3)(B), including the number of such applications completed within 90 days pursuant to that section. There are two types of identical or substantially similar applications – new products and label amendments that require no data review. The former have been called in the past “Fast Track New Products,” while the label amendments are still called “Fast Track Amendments”.

Identical or substantially similar new products (formerly “Fast Track New Products”) are subject to registration service fees and have mandated decision review time frames under PRIA, and processing costs are also supported by maintenance fees. Identical or substantially similar products, or Fast Track New Products, are subdivided into separate fee categories, all of which have time frames greater than three months. With the passage of PRIA 3, the decision review timeframes for identical or substantially similar product categories (R300, A530, B660 and B710) were increased from 3 months (in PRIA 2) to 4 months (in PRIA 3). The number of identical or substantially similar products (A530, B660, B710, and R300) completed in FY’14 was 172, of which 28 were completed within 90 days; 130 were completed within their PRIA time frames, and 14 were completed late. The number completed in FY’14 was less than that in FY’13 (172 versus 227).

An additional 67 identical or similar new products in categories (A531, A532 and R301) were completed (49 within the PRIA statutory time frame, 11 within their due date extension timeframes and 7 late). The number completed in FY’14 was less than in FY’13 (67 versus 90).

In response to the government shutdown in October 2013, the Agency eschewed renegotiating PRIA due dates in favor of utilizing that time and resources to reduce the backlog created by the shutdown. This has been referred to as the “short term strategy” which was in place from the middle of October 2013 to the middle of January 2014. Consequently, the late completions described above should probably be considered in view of this “short term strategy”.

“Fast Track Amendments,” label amendments that required no data review, are not subject to registration service fees. In FY’14, the agency completed 2,234 fast track amendment decisions (antimicrobial – 670, biopesticide - 321, and conventional -1,243), which was slightly greater than in FY’13 (2,194) but less than in FY’12 (2,555) and FY’11 (2,899).