BPPD Label Amendment Checklist

Fast Track ☐ and PRIA Actions B650 ☐, B680 ☐, B681 ☐, B730 ☐, B890 ☐ &B900 ☐

EPA Reg. No.: **RAL:** **Application Date:**

#	Check list Item	Yes	No
1.	**Application Form** (EPA Form 8570-1) - signed & complete, including package type? **IF NO, STOP**! Call applicant and have them correct application and resubmit.		
2.	**Final printed labeling** received for previous action? **IF NO, STOP!** E-mail applicant and request final printed labeling (FPL).		
3.	Does the registration notice have terms/conditions (ex: storage stability data)? If so have the terms/conditions been met?		
4.	If new use sites are being added, are they subject to OPP's process for public involvement in pesticide registration actions?		
5.	**Data and Data Matrix** present. (EPA Form 8570-35) NA ☐ If Fast Track, check to see if original registration supported by data, formulators exemption, etc.		
a.	Using Selective Method? [**IF NO, SKIP to item 4 and note that data matrix should be used for the cite-all method to indicate the companies to whom offers of compensation were made.**]		
b.	Complete Data Matrix supporting both the product registration and the proposed amendment. Minimum Data Matrix for registration includes: Product specific Acute Toxicity and Product Chemistry data, plus Efficacy data for public health pests claimed on label.		
c.	Adequate product specific data?		
d.	Registered source used for active ingredient? **IF YES**, **SKIP to ITEM 4.** (If active ingredient is from a registered source (manufacturing-use product), generic data should be satisfied by registered source.) **If NO or if use not supported by registered source**, generic data is necessary.		
e.	If new data submitted: data passed PR Notice 86-5 for formatting and MRID # assigned?		
f.	Public copy of Data Matrix provided? (PRN 98-5)		
6.	**Certification with Respect to Citation of Data** present. (EPA Form 8570-34): See 40 CFR 152.80-98 and PR Notice 98-5 [If no data are required or submitted, a Certification with Respect to Citation of Data form isn't needed. This is often true for minor amendments.] NA ☐		
a.	Did applicant check a Method of Support?		
b.	General Offer to Pay checked for Cite-all Method or Cite-all under Selective Method?		
c.	Is the form signed and dated?		
d.	Check form and Data Matrix. Are Exclusive Use data cited from other sources?		
	IF YES, is the required authorization letter included in application? NA ☐		
7.	**Label(s) Review** **Date of Label Review:**		
a.	Label(s) in conformance with current *Label Review Manual* and appropriate REDS.		
b.	Labeling statements and claims are supported by Acute Toxicity, Product Chemistry data (or acceptable waivers). Acceptable efficacy studies support public health pests claimed on label.		
c.	Nominal concentration of active ingredient shown in ingredients statement.		
d.	Viability included as sub-statement of Ingredient Statement (if live microbial, i.e., cfu/gram).		
e.	Storage and disposal instructions agree with container types listed on application form.		
f.	Unique Product Name for Same Company (Check OPPIN).		
g.	Does CSF list peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, or wheat commodities? **If YES**, RAL must evaluate label use directions for compliance with 40 CFR 180.1071.		

h.	Does label bear “National Organic Program” (PR Notice 2003-1) or OMRI claims?		
	If YES, National Organic Program or OMRI claims approved by Chris Pfiefer? NA ☐		
i.	Labeling is acceptable. Corrections or changes are NOT necessary.		
j.	Comments:		