U.S. Label Action Checklist and Approval Form

To initiate this form, do the following (DO NOT delete or alter any section of this form):

- **Place an X in the box under Type of Action (see below).**
- **Fill in product name, active ingredient(s), and EPA registration number.**
- **If form is for a Section 18 or 24(c) label, fill out the appropriate section. If form is not for Section 18 or 24(c) label, ignore these sections.**
- **Fill in the person's name next to the appropriate role for the product.**
- **List the label changes on the last page of the form.**
- **Send the form via e-mail to the Regulatory Specialist for the product.**

To approve this form, do the following:

- **Fill out the Key Questions/Information Required for your role.**
- **Put the date of your approval in the Approval Date column on the same line as your name.**

Note: This form is to approve the proposed action, not review/approve the draft or proposed label. <u>All</u> sections of this form <u>must</u> be completed prior to initiation of draft labeling by the Regulatory Specialist.

Type of Action: (place an X in the box to the left of the appropriate action)

[FORMCHECKBOX] Creation of Section 3 main label

[FORMCHECKBOX] Creation of Section 3 supplemental label

[FORMCHECKBOX] Creation of Section 18 label

[FORMCHECKBOX] Creation of Section 24(c) label

[FORMCHECKBOX] Creation of Section 2(ee) label

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[X]

[FORMCHECKBOX] Amendment of Section 3 main label

[FORMCHECKBOX] Amendment of Section 3 supplemental label

[FORMCHECKBOX] Amendment of Section 18 label

[FORMCHECKBOX] Amendment of Section 24(c) label

[FORMCHECKBOX] Amendment of Section 2(ee) label

Product Name: [PAGE][FORMTEXT] **a.i.:** [FORMTEXT]
EPA Reg. No.: [FORMTEXT]

If Section 18, what is the objective: [FORMTEXT]
If Section 18, who is sponsoring (e.g., state, commodity groups): [FORMTEXT]

If Section 24(c), what is the objective: [FORMTEXT]

Approval: (include date in Approval Date column in the row containing your name)

Role	Name	Input/Comments	Approval Date
Product Technology Specialist	[FORMTEXT]	[FORMTEXT]	[FORMTEXT]
Marketing Specialist	[FORMTEXT]	[FORMTEXT]	[FORMTEXT]

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Tech Expert	[FORMTEXT]	[FORMTEXT]	[FORMTEXT]
Federal Regulatory Manager	[FORMTEXT]	[FORMTEXT]	[FORMTEXT]
State Regulatory Manager	[FORMTEXT]	[FORMTEXT]	[FORMTEXT]

Key Questions/Information Required (Information Provided by Tiger Team):

Product Technology Specialist

• Use directions for proposed use or list of proposed label changes, including those listed on label bulletin board (**Yes/No**): (Provide text/create list on page 2 or embed Word document on page 2)	[FORMTEXT]
• **Sec 18/24(c) labels only:** Include Special Conditions of Use (which was previously called Waiver of Liability) on label (**Yes/No**):	[FORMTEXT]

Marketing Specialist:

• Reason for proposed change(s) or creation of label:	[FORMTEXT]
♦ Mandatory or Regulatory initiated (e.g., PR Notice, RED, state req., etc.):	[FORMTEXT]
♦ Commercial (new crop, rates, pest, etc.): (New crop, rates, pest will be submitted as a supplemental label)	[FORMTEXT]
• Molecule status per current year Business Line Matrix (Invest, Grow, Defend, Manage for Cash):	[FORMTEXT]
• Projected market value of proposed change(s) or use(s):	$[FORMTEXT]
• List of state(s) to be registered in:	[FORMTEXT]
• Expected/desired sales promotion date:	Date: [FORMTEXT]
• **Sec 3 main label only:** Does action involve a supplemental distributor (**Yes/No**):	[FORMTEXT]
If yes, will DAS commercialize label too (**Yes/No**):	[FORMTEXT]
• **Sec 3 main label only:** Will there be any post-approval label activities, e.g. registration of ABN, roll same changes onto ABN label, a subset of registered uses commercialized (Federal Regulatory Manager to be consulted) (**Yes/No**)	[FORMTEXT]
If yes, provide specific details:	[FORMTEXT]

Technical Expert (Review and Comment with Input from Product Technology Specialist):

• Availability of efficacy and/or crop safety data required by Cal DPR?: (Data must be supplied to Regulatory (State Regulatory Assistant) before label before product(s) can be registered in the states.)	[FORMTEXT]
• Has risk/benefit review been conducted (e.g., crop safety, efficacy) (**Yes/No**):	[FORMTEXT]
• Risk score from Decision Tree Risk Matrix (≤45, between 45 and 65, >65): (If score is greater than 65, Special Conditions of Use language may be required.)	[FORMTEXT]

Federal Regulatory Manager:

• If changes are mandatory, can other changes be made simultaneously (**Yes/No**):	[FORMTEXT]
• Any outstanding data requirements at EPA (**Yes/No**):	[FORMTEXT]
• **Sec 3 labels only:** Last EPA label submission date: (Note: No overlapping label amendments are allowed.)	Date: [FORMTEXT]
• **Sec 3 labels only:** Target EPA submission date: (Note: Nominal review time is 90 days for amendments requiring no data; up to 2 years for new crops with PRIA.)	Date: [FORMTEXT]
• Is proposed use consistent with federal regulatory strategy (**Yes/No**):	[FORMTEXT]
• Amendment cost – EPA fee for service:	$[FORMTEXT]
• **Sec 3 main label only:** Will there be any post-approval label activities, i.e,.	[FORMTEXT]

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registration of ABN, roll same changes onto ABN label, a subset of registered uses commercialized (Marketing Specialist to be consulted) (**Yes/No**)	
If yes, provide specific details:	[FORMTEXT]

State Regulatory Manager:

• List any special considerations (e.g., PPE for urban pest, special state agreements, etc.):	[FORMTEXT]
• State registration fees associated with this action:	$[FORMTEXT]
• Any outstanding data requirements in the state(s):	[FORMTEXT]
• All necessary data/information will be assembled and available to support application: (Data must be supplied to Regulatory (State Regulatory Assistant) before product(s) can be registered in the states.)	[FORMTEXT]
• **Sec 18/24(c)/2(ee) labels only:** Target submission date to state	Date: [FORMTEXT]
• **Sec 18 label only:** Is there pending Section 3 (**Yes/No**):	[FORMTEXT]
♦ If so, anticipated approval date:	Date: [FORMTEXT]

Listing of proposed label change concepts to be provided by Product Technology Specialist (e.g., addition of a pest, change of buffer zone, application timing etc.)

1. [FORMTEXT]
2. [FORMTEXT]
3. [FORMTEXT]

[FORMTEXT]

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