Common reasons a notification may be rejected (updated 10/2/24)

This document contains common reasons the registration division rejects notifications. This list was generated using input from RD staff and analyses of notification rejection reasons from FY2023 and FY2024.

The following list is not meant to change or expand upon PR Notice 98-10, the Label Review Manual, or EPA's regulations concerning labeling, but is meant to communicate the most common errors the Registration Division encounters when reviewing notifications. The goal of this document is to identify these common issues for applicants to increase notification submission quality and decrease the number of rejected notifications. In addition to avoiding the issues identified below, clearly describing the action in the application form and cover letter assists the Agency in timely processing of the actions (see Cover Letter Suggestions for Notifications and Fast Track Amendments).

Common reasons a label notification may be rejected:

1. Adding public health pests.
2. Adding or changing any additional label language other than what was highlighted as a change or outlined in cover letter (*see* 40 C.F.R. § 152.46(c)). An exception would include language added via non-notification since the last EPA approved label.
3. Adding mitigation language that should be added via amendment (see PR Notice 98-10, page 8 (II)(N)(3)).
4. Adding false or misleading alternate brand names (*e.g.*, names already being used by another product or names that imply safety or enhanced efficacy) (*see* 40 C.F.R. § 156.10(a)(5)).
5. Request for "clarifications" for Directions For Use and/or Precautionary Language that result in an expansion of label language of those sections.
6. For labels that have a toxicity category I or signal word of "DANGER," the First Aid statements must remain on the front panel (*see* 40 C.F.R. § 156.68). Therefore, it is not allowed to add referral statements to other panels for these products.
7. Adding marketing statements with too many brackets denoting optional language, such that EPA cannot evaluate whether the claim is false, misleading, or confusing.

Common reasons a CSF notification may be rejected:

1. Adding a new registered technical source of active ingredient that does not support the uses on the label.
2. Changing a source of active ingredient that changes the nominal amount or is outside certified limits.
3. Changing a source of inert ingredient that is outside the certified limits.
4. Missing data matrix for the technical product when company is using its own source of technical ingredient (not purchased from another company, and thus does not qualify for a formulator's exemption under 40 C.F.R. § 152.85(a)).

5. Combining label and CSF notifications can increase complexity; for example, if EPA rejects the label, it will also reject the CSF portion of any notification submitted under the same action.
6. Submitting a Minor Formulation Amendment (MFA) as a notification.
7. Adding a new establishment site for a technical product, or to an end use product formulated with an un-registered source of active ingredient; such changes are subject to PRIA.
8. Inclusion of unknown/uncleared tradenames/inerts.
9. Ingredients not adding up to 100% within the percent by weight column.
10. Including a range instead of a single value for density in Box 7.
11. Including an inappropriate range for pH in box 8 (range should be no more than one pH unit, with the exception of pH values in the neutral range, where a pH value range of 2 pH units would be accepted (i.e., pH 6.0 to 8.0)).
12. Not including the EPA Reg # on the CSF for antimicrobial preservatives.
13. Not providing a company contact and phone number when the company name and address is listed in Box 2 rather than the EPA establishment numbers.

Common issues related to forms:

1. Container type left blank on application or changing the container type on the form and it doesn't match the label.
2. Missing and/or inaccurate information in forms or missing forms altogether (*e.g.*, formulator's exemption form).
3. Listing only international contact information versus domestic consultant (see 40 C.F.R. § 152.50(b)(1)).
4. Leaving off the following self-certification statement: "This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 C.F.R. § 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 C.F.R. § 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA."