

Cover Letter Suggestions for Notifications and Fast Track Amendments

This document contains suggestions on ways to write cover letters for label and CSF notification and fast track amendment actions, to assist the Agency in the timely processing of those actions. In addition, an example cover letter is provided. Please note that all the following are recommendations and not requirements.

- Explain the nature of the changes being proposed (*e.g.*, new production site, new source of active ingredient, new non-public health pest related marketing claims, etc.). Only stating that it is a revised CSF or revised label is insufficient detail for the Agency to quickly discern the nature of the changes and slows down the Agency review process. In addition, the following information is helpful for the Agency's review:
 - o Clearly identify the submission as a label notification, label fast-track amendment, CSF notification, minor formulation amendment or CSF fast-track amendment and make sure that the actions are consistent with what is outlined within PR Notice 98-10.
 - o For label actions adding directions for use "me-too'ed" from already approved labels, please include the registration numbers of the cited products. In addition, for data compensation purposes, provide a data matrix that addresses the generic data requirements for the active ingredient, in support of the me-too use or indicate that the uses are covered by the Formulator's Exemption.
 - o For CSF actions, please use the inert finder database ([Inert Finder Website](#)) and confirm whether the proposed inerts are cleared for the intended use (*e.g.*, 'food use' or 'non-food use').
 - o For CSF actions, please list which approved CSFs are currently in company files.
 - o Please state how data compensation has been addressed.
 - o For notifications, include the PRN certification statement (*e.g.*, "This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR § 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 statements to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR § 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.")
 - o For the ease of assigning reviewers to work on actions, product managers find it helpful if when you are submitting actions making changes similar to those in other recent submissions that you reference those other actions in your cover letter. If possible, the same reviewer will be assigned all those actions since they will be familiar with the changes.
- Include a list of documents being submitted with the submission. Documents recommended for EPA's review include:
 - o Highlighted label for label notifications and highlighted and clean versions of the revised label for fast-track label amendments.
 - o Application form.

- Proposed CSFs. Please state the dates of the CSFs and whether they are the basic CSF or one of the alternate CSFs. For CSF notifications, please highlight the changes on the proposed CSFs.
 - Courtesy copy of already approved basic CSF. Providing what you have on file as the current basic CSF will increase the efficiency with which the Agency can review the submission.
 - Data matrix, certification with respect to data citation, offer to pay letters and/or formulator's exemption forms, if needed.
 - If using a consultant, please include an Agent authorization letter.
- Consider including a paragraph towards the end of the cover letter that addresses product file maintenance and lists older notification and amendment actions that are still pending with the Agency.
- When listing the actions, please state what type of submissions are currently pending (*i.e.*, label notification, label amendment, CSF notification, CSF amendment, PRIA amendment) and the date of submission for each. For each action, please specify a desired path forward. For example:
 - Action no longer needed and can be withdrawn.
 - Original action is superseded by new action and can be withdrawn.
 - The action is still of importance to the company, therefore it is requested the reviews be combined, if possible. Label and CSF actions must be reviewed separately and cannot be combined.
- Close the letter with two points of contact and their email addresses. This is helpful if one of the contacts is unavailable.

Example Letter

Submitted Electronically via CDX Portal

October XX, 2023

Document Processing Desk (AMEND)
Attn: John Doe, PM XX
Registration Division
U.S. Environmental Protection Agency
Office of Pesticide Programs (7101M)
William Jefferson Clinton Building
1200 Pennsylvania Ave., N.W.
Washington, DC 20004

Subject: Pesticide Product Name
EPA Registration No. XXXX-XX
Fast-track CSF Amendment

Dear John Doe,

ABC Regulatory Consultants, Inc., as agent for XXX LLC, is respectfully submitting a fast-track amendment to revise alternate CSF 1 and to add a new alternate CSF 2 to the above referenced product. The purpose of the submission is to add an alternate production site to box 2 and to add multiple new technical sources of active ingredient. All use sites on the end-use label can be found on the new technical source labels and the Formulator's Exemption is applicable (*i.e.*, the technical was "purchased from another person"). All inerts have been cleared through EPA's inert ingredient database and are approved for food use. The currently approved CSFs on file include a basic CSF dated 07/11/20XX and an alternate CSF 1 dated 11/10/20XX.

In support of this request, the following documents are being submitted via the CDX Portal:

- Letter from XXX LLC, appointing ABC Regulatory Consultants as its agent
- Application for Pesticide Amendment (EPA Form 8570-1)
- Proposed CSFs (EPA Form 8570-4) – Alt. 1 & 2 dated 10/14/20XX
- Courtesy Copy of Currently Approved Basic CSF dated 07/11/20XX
- Formulator's Exemption (EPA Form 8570-27)

Product File Maintenance

Upon review of the product file, we find that there are three currently pending CSF notification or amendment actions with the Agency. See below for details. If the Agency files do not match company files in terms of pending actions, please let me know.

- CSF Notification dated 06/11/20XX
 - o Upon review, this action is no longer needed, therefore can be withdrawn.
- CSF Amendment dated 09/20/20XX

- This action concerns a revised alternate CSF 1, which is superseded by this submission.
- CSF Amendment dated 11/01/20XX
 - This action concerns a revised basic CSF. This action is still needed by our company, therefore we request, if possible, for its review to be combined with this most recent submission.

If you have any questions about this submission, please contact the undersigned at steve@abiconsultants.com or (XXX) XXX-XXXX. It is suggested that you also copy Jane Smith at jane@abiconsultants.com on all emails.

Sincerely,

Steve Jones