# Product Licensing Plans & Critical Path Agreements

## Overview

Every reviewer is expected to prepare and maintain a product licensing plan for each new product proposed for licensure/permit. The plan in the prelicense stage is a list of all projected submissions needed for licensure and a tracking system for their completion. It is a living document and must be updated as the need for follow-up submissions arises. It also contains specific agreements (particularly critical path agreements) made during the licensing process. A complete and up-to-date plan facilitates the transfer of on-going licensing efforts between reviewers. The plan is reviewed by the CVB Director before signing a license/permit.

Post-licensure, the plan is used to note key post-license approvals and product changes that have ongoing relevance for the life of the product. This includes, but is not limited to, confirmation of dating, label claim changes, or reformulations. The plan also serves as a reference when the firm elects to develop related products.

A second important objective of a licensing plan is to enable the calculation of meaningful and defensible times to licensure. Akin to a lawyer's billable hours, reviewers are expected to account for every prelicense submission they handle, no matter how trivial, on the licensing plan. These data are then used to calculate a total time to licensure (receipt of first submission to date of product licensure) and an active time to licensure (count of days where at least one submission was actively being processed by the CVB).

## References

CVB Notice 11-12: Product Licensing Plans

[redacted]

Template—Critical Path Agreement (see Appendix 1)

[redacted]

## Developing the plan

A license plan may be created in LSRTIS as soon as the reviewer feels that the firm is reasonably serious about moving forward with a product. This can vary by reviewer, but should occur no later than product code assignment. If the plan is created before a code is assigned, LSRTIS will accept Unassigned place markers for Est and/or Product Codes. Ensure that the Plan Description contains sufficient detail to distinguish one unassigned plan from another, and be sure to update the plan record with specific codes when they are assigned. If the plan is created at the time the product code is assigned, the reviewer is responsible for checking the ML history for relevant submissions originally processed as Unassigned and adding them to the plan.

The reviewer should invite the license applicant to participate in a discussion of the product licensing plan. The process is intended to be interactive, but applicants may elect to take

different degrees of involvement in the plan. Even if the applicant elects to take no role at all, the reviewer is expected to create and maintain a license plan in LSRTIS.

If the firm provides a development plan of their own, note it on the licensing plan in the specific line item provides for Firm's Plans in the "Other" section of the licensing plan. Also note in the mail log with a Firm's Licensing Plan tag. This allows us to monitor how many firms provide their own development plan to aid in the preparation of the CVB's licensing plan. This does not exclude the possibility of referencing the same submission on another line(s) of the licensing plan, as applicable.

A checklist of common line items to be considered for a plan is available during the LSRTIS license plan creation process. This is not an exhaustive list, and additional line items for should be added as applicable. If the product is the first for a new establishment, include submissions pertaining to the issuance of the establishment license.

**Critical path agreements**

Frequently agreements are made between the CVB and the applicant regarding the approach to fulfill a specific licensing requirement or to obtain an exemption. Often such agreements arise from verbal discussions, but it is imperative to document final agreements in writing and note them in the licensing plan. Otherwise, issues may arise from differences in opinion over what was said. It is the reviewer's responsibility to maintain written notes of verbal discussions and to place copies of critical notes in either a ML or phone log record. Reviewers are encouraged to prepare formal written correspondence to the applicant to document key discussion points.

As an additional measure, applicants may request Critical Path Agreements on any point that may be considered novel, a departure from accepted procedure, or subject to multiple choices. A Critical Path Agreement is a means of formalizing a regulatory agreement and is the CVB's assurance that, barring any product quality or animal health concern that was not recognized at the time of the agreement, the CVB will not change its perspective on the issue. Critical Path Agreements are product specific and cannot be automatically extrapolated to future licensing efforts. They also are agreements *in principle* and do not guarantee acceptance of all possible data outcomes.

It is the responsibility of the applicant to request a Critical Path Agreement. Requests must be made in an official submission (not email). The submission should contain a description of their understanding of the agreement, along with any relevant data that were used to justify the agreement. The reviewer then responds to this submission with correspondence specifically formatted as a Critical Path Agreement.

The template for Critical Path Agreement correspondence may be accessed in Appendix 1. The correspondence must contain a description of the agreement, followed by standard boilerplate text regarding the nature and applicability of Critical Path Agreements. Note Critical Path Agreements in the mail log with a Critical Path Agreement tag.

**Creating and updating the product licensing plan**

Stepwise instructions for creating and updating licensing plans in LSRTIS are found in the [redacted]

Plans created prior to February 2015 were created on Excel spreadsheets and migrated to LSRTIS. Read-only copies of those Excel files remain available for historical reference until February 2016 at [redacted]

Although the Licensing Plan User Documentation contains info on how to operate the software, the following subsections contain additional business rules and guidance on developing meaningful plans:

a. Plan Description field:

This field is intended to include any information that aids in determining licensing requirements or otherwise assists the reviewer in understanding product relationships. Do not simply add the True Name. Describe the aspects of this product that are unique and the aspects that are the same as other products. Examples:

- [redacted]

b. Line Item recommendations

- Create line items for every anticipated submission. If you started with a default line item auto-generated when you created the initial plan record, update the Line Item Description so it is specific enough to be meaningful.
- Create separate line items for protocol submission vs. final study reports.
- Link ML items to license plan line items *as the submissions arrive*. This allows you the system to auto-track the status of review. Once you link a ML item to a licensing plan line item, there should be no further need for a manual update unless you need to add an internal comment.
- The line item status will be listed as "completed" when review of the ML item is done, regardless whether the submission was sufficient to fulfill a regulatory requirement. To ensure there is no confusion:
    - Enter a concise summary of your *regulatory decision* in the Synopsis of Reviewer Response field in ML records so that this will be reflected on the license plan.
    - Create a new line item for a repeat submission as soon as you know one will be needed. Don't wait until the repeat submission arrives. This makes it clear that

the licensing requirement is not yet fulfilled and you are expecting something more.

- Except for a new firm licensing its first product, generally some licensing requirements have already been fulfilled, based on the licensure of other products. It is important, however, to capture these requirements as Notes in the plan, to document how the requirements were fulfilled. Cite specific historical studies/submissions by ML as much as possible, but if historical records are not available, cite the licensed product code that was used as the basis for considering a particular licensing requirement fulfilled.
  - Examples [redacted]

c. Business rules for filling out License Plan Line Item data fields

Line items selected from the default list and auto-generated during initial license plan record creation must be updated to activate the line item status. For line items added after the initial plan is created, all necessary information is required before the initial save of the line item. For each line item, you must designate whether the line item is a note, counts as active time to licensure, or should print on external reports. Until you do this, the status will be "No status."

- Should it be a Note?

Notes are for items/reminders for which you are not expecting a new submission from the firm. The line item status of notes never changes.
They can display on external reports or be solely for internal use.

Examples:

- Confirming a licensing requirement was fulfilled by a related, previously licensed product (e.g., "IBR Master Seed XYZ was approved 8/28/1973"; "adjuvant the same as licensed product XXXX.XX")
- An internal reminder (e.g., "need to remember to issue license with restriction X")
- To indicate certain license requirements are TBD at this time

- Should it count as active time to licensure?

A ML item can count as active time to licensure for only one product. If there is a product line being licensed and a submission applies to all, typically it is active on the largest combination product's plan. This does not prevent you from listing the same ML on all

applicable products, but "Counts as Time to Licensure" needs to be set to No on the remaining plans.

The system will prevent you from designating two plans as active for one ML item. If you get this error message, you will have to fix the conflict before you can save your line item.

If not dealing with a product line, most new submissions will count as active time to licensure. Exceptions include items that are held open pending licensure:

- License applications (APHIS 2001, 2003, 2005)
- Acceptable labels that arrive ahead of the final submission needed for licensing. Labels that can be processed immediately, either because they are to be sketched or because they are the final piece prior to licensure, should count as active. Only those labels that must be held for licensure do not count.

Historical submissions do not count as active time on products licensed later. Example: A master seed approved for another product does not count as active time for related products developed years later. To assist you in selecting the correct value, any line item designated as Note cannot count as active time to licensure.

- What is the difference between an Internal Comment and preventing an item from printing on external reports?

If you select No for "Print on External Reports", then the entire line item will not appear on a license plan report intended for the firm.

An Internal Comment allows you to note something about the line item for CVB use only while still allowing the remaining portion of the line item record to appear on external reports.

d. Plans for breakout products

It is not necessary to complete a full plans for breakout products that are licensed on the basis of a parent product. For such product families, create a complete plan for the parent product. For each breakout, initialize a plan with the establishment number and product code, then include in the description that it is a breakout of Code XXXX.XX. Enter the Parent Est/Product Code in the specific fields provided. *At a minimum*, use this "child" plan to track submissions applicable only to the breakout product (e.g., Code Assignment, Outline of Production and labeling). Refer the reader to the plan for parent Code XXXX.XX for the remainder of the licensing plan.

This does not preclude a reviewer from listing submissions on each plan to which they apply, if that is their preference, although each ML can count as active time to licensure on only one plan.

**Requests for plan**

Applicants may request a copy of the current plan at any time. Plan data suitable for printing or conversion to pdf for electronic transfer are available. Ensure that only the **External Plan report** is sent outside the CVB. Copies may be provided as hard copy or electronically. Reviewers are expected to turn around industry requests for updated plans [redacted] In the event that the reviewer is out of the office, industry may direct requests to support staff, who can provide copies of the current plan

In the not-so-distant future, firms will likely be able to run a licensing plan report on demand through an electronic portal. This means it is everybody's best interest to keep their plans current (including linking MLs as they arrive) and making sure the data that appear on the report are suitable for distribution at all times. Ensure the data are appropriate as they are entered at the source interface (plan screen OR ML screen). Do not depend on the opportunity to clean things up once the report is printed.
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**Use of Plan to Calculate Time to Licensure**

The licensing plan is used to calculate a meaningful measure of the time to licensure. Reviewers are expected to list every submission pertaining to a product on the plan so that the review time measure is accurate.

*Active Review Time to Licensure*: The list of mail log numbers flagged as counting toward active time to licensure is merged with turnaround time data from the mail log database. From this, a count of work days with at least one pending submission (active review time) may be calculated.

*Total Time to Licensure*: The mail log numbers will also be used to determine the work days elapsed from the date of receipt of the first submission to licensure. From this, total time to licensure can be compared to active review time. The difference reflects the amount of time elapsed during which the CVB had no pending submissions for a given product, such as might

happen if a particular product is low priority for a firm and the time to licensure is protracted for reasons beyond CVB control.

## Appendix 1 Critical Path Agreement Template

Date

Establishment address

Dear xxx,

<Usual first paragraph with product identifiers>

This letter represents a critical path agreement regarding the licensing plan for this product(s):

<description of the issue and the agreement made, including any associated caveats and conditions>

Our concurrence means that, considering current regulations and policy, we fundamentally agree with the proposal described above. It represents a commitment that we will not later alter our perspectives on this issue for this particular product unless a product quality or animal health concern appears that we did not recognize at the time of assessing this issue. Because this concurrence does not extend to any subsequent changes you may wish to make to this proposal, you may wish to seek our concurrence on any proposed changes.

closing