



Note for file

Purpose

This form should be:

- used to record details of the evaluation conducted during the review process of Listed medicines **s22**
- used as part of a decision making process; and
- completed electronically and saved to the relevant file in TRIM.

Type of event

Evaluation record

Topic

s22

s22

Key points

Q1. Medicine name, AUST L and sponsor name

s22

Q2. Did the sponsor respond to the RFI **s22**

Yes

☐

s22

No

☐

s22

Q3. Details of information provided

Describe the type of information that was provided, e.g. chemical data, risk assessment, etc.

Q4. Evaluation

Describe your evaluation process, considerations, deficiencies found, etc.

Q5. Do the labels provided include the three required warning statements?

Yes

☐

If yes, proceed to question 7

No

☐

If not, please provide details and proceed to question 6

Reference/Publication #

Q6. Is there any mitigating reasons provided why a recall would not be necessary?

Yes ☐

s22

No ☐

s22

Q7. Does the medicine have other evident safety-related issues that are not related to the fennel related warnings?

No ☐

Yes ☐

s22

Issue	Legislative contravention

s22

s22

CATEGORY – CERTIFICATION

Q9 s22, please select the s22 compliance breaches found in this product.

s22

☐ 26A(2)(a) – [C001] – The medicine is not eligible for listing

☐ 26A(2)(b) – [C002] – The medicine is not safe for the purposes for which it is to be used ☐

☐ 26A(2)(cb) – [C005] – The manufactured medicine contains ingredients that do not comply with the listing requirements for those ingredient(s) specified under paragraph 26BB(1)(B)

CATEGORY – OTHER

☐ 30(1)(g) – [T006] – The sponsor made a statement in, or in connection with, the application for listing of the medicine that was false or misleading ☐

☐ 30(1A)(a) – [T007] – The medicine is not eligible for listing ☐

☐ 30(2)(a)-s – [T012] – The safety of the medicine is unacceptable

Q10. Follow-up action

Describe what action was taken, sponsor's response and include relevant TRIM links

Q11. Final Decision

s22

s22

Author details

(include contact details and date note prepared)

Delegate details

(include details when satisfied with the assessment above)
