



s22

Summary of Proposal to Cancel Response

Product			
Sponsor		TRIM Ref	
Delegate		'Proposal to cancel' response due date	

s22

Has a response to the proposal to cancel letter been received?

☐ Yes ☐ No

s22

Date	Summary

What issues were raised in the P2C and how have these been addressed?

Description of Breach	Actions to address breach
s22	s22
s22	s22

Do these actions rectify the identified breaches?

☐ Yes ☐ No

s22

☐ ☐ ☐

What do we need to see from the sponsor before we are satisfied to conclude?

Required?	Proposed	Implementation date	Completed
<input type="checkbox"/> Updated Actual label	<input type="checkbox"/>		<input type="checkbox"/>
<input type="checkbox"/> Update to ARTG entry	<input type="checkbox"/>		<input type="checkbox"/>
<input type="checkbox"/> Updated Manufacturing documentation	<input type="checkbox"/>		<input type="checkbox"/>
<input type="checkbox"/> Updated evidence table	<input type="checkbox"/>		<input type="checkbox"/>
<input type="checkbox"/> Cancel the listing from the ARTG	<input type="checkbox"/>		<input type="checkbox"/>

Do their proposed actions create any other potential compliance breaches?

☐ Yes ☐ No

Describe

Other comments/Relevant considerations

- <Anything else the Delegate should be aware of>

Options s22

☐

Option 1 -

☐

☐

Name

Signature

Date

Recommendations

☐ Conclusion ☐ Cancellation ☐ Request further information ☐ Other (describe)

Reasoning

Name

Signature

Date

s22 [Redacted]

Delegate's Decision

☐ Agree with recommendations ☐ Propose alternative (describe)

Describe	<only if proposing alternative>		
Name			
Signature		Date	

Relevant documents

s22 [Redacted]

[Redacted]

[Redacted]

TRIM Ref	Document Name
	ARTG Record Summary
	Signed Proposal to cancel letter
	Proposal to cancel response
	Email from sponsor – time frame for implementation