Recalls Unit Notification Screening Sheet   **Recall RC-2011-RN-00** _3̲5̲5̲-̲3̲_

Recall Coordinator ___Deeg___   Date _31/3/11_

Is the product in the notification a therapeutic good? *(i.e. it is not a food, cosmetic or excluded good)*

[✓] YES - continue with checklist ↓
[ ] NO = *'Not a therapeutic good'* →Screening complete (Refer to _____)

Has a tampering incident of an Australian supplied product been identified?

[✓] NO - continue with checklist ↓
[ ] YES - see Tampering SOP - 'Sponsor Non Recall Action' path →Screening complete (assessment)

Are there any similar reports on RAMP?

[✓] NO - continue with checklist ↓
[ ] YES - order any relevant files to review previous actions, identify duplicate entries or identify trend
→Outcome   [ ] Unique notification - continue with this checklist ↓
              [ ] Not relevant _____   →Screening complete (refer to e-file)

Does the notification refer to a possible or actual <u>recall</u> of an Australian supplied therapeutic good?

[✓] YES - continue with checklist ↓
[ ] N/A - Sponsor/manufacturer advises no Australian supply
       →**Screening complete** (refer to delegates – send email 'Overseas recall not affecting Australia')
[ ] NO – seek information from ARTG, Client, TGA library databases or Internet (Print any relevant results)
→Outcome   [ ] Medicine Defect* →Screening complete (refer to Raymond Wilson – <u>no RAMP entry</u>)
              [ ] Device Incident* →Screening complete (refer to IRIS)
              [ ] Illegally supplied product →Screening complete (refer to RCU)
              [ ] O/S GMP failure →Screening complete (refer to OMQ)
              [ ] Export list does not include Australia →Screening complete (refer to e-file)
              [ ] An AUSTRALIAN supplier CANNOT be identified →Screening complete (refer to e-file)
              *includes adverse reactions, notices of 'out of stock' or cessation of marketing

Has the sponsor started any market action in Australia?

[✓] NO - continue with checklist ↓
[ ] UNKNOWN *(Overseas Recall)* → 'Sponsor Non Recall Action' path → Screening complete (assessment)
[ ] YES → 'Recall not notified to the TGA' path → Screening complete (assessment)

What market action is proposed?

[ ] Recall action *(i.e. Recall, Recall for Product Correction, Hazard Alert)*
       → 'Sponsor Recall Action' path - continue with checklist ↓
[✓] Non Recall action *(i.e. Safety Alert, Product Notification, No Action, Product Withdrawal, Quarantine)*
       → 'Sponsor Non Recall Action' path - continue with checklist ↓

Have the six essential sets of information been provided in at least summary form?
Problem   Product   Product Distribution   Hazard   Proposed Action & Timeline
[ ] YES →Screening complete (assessment)
[ ] NO - seek information from the sponsor. Details _____
→ Outcome   [ ] information provided →Screening complete (assessment)

See attached letter.   Date 02/03/2011
No action required.
This may be placed on a "referred" file (SI - Devices)
       + appropriate. SD 31/3/11