



Appendix C: Request for Human Drugs Reconsideration Template

| Section A – Administrative Section | | | |
|--|--|--------------------------|------------|
| Contact Person for this Request for Reconsideration | Name: | | |
| | Telephone: | | |
| | Facsimile: | | |
| | E-mail: | | |
| Date this form is completed | | | |
| Brand (Proprietary) Name, or Licence Application/Amendment Subject | | | |
| Manufacturer/Sponsor Name | | | |
| Proper, Common or Non-proprietary Name of Medicinal (Active) Ingredient(s) | | | |
| Dosage Form(s)/Strength(s) | | | |
| Route(s) of Administration | | | |
| Section B – Submission Tracking Identifiers | | | |
| Submission Type (check one) | NDS ANDS CTA Application for Authorization Application for Authorization - Amendment | S/NDS S/ANDS CTA-A | NC DINA |
| Control Number | | | |
| CR File Number | | | |
| Decision for which Request for Reconsideration is filed (check one) (attach copy of decision letter) | Screening Rejection Letter (including New Drug Letter) Notice of Deficiency – Withdrawal Letter Notice of Non-compliance – Withdrawal Letter Not Satisfactory Notice Notice of Insufficient Information –Withdrawal Letter Notice of Refusal Rejection of Accelerated Licence Amendment Submission | | |
| Date of issuance of decision for which Request for Reconsideration is filed | | | |

Section C – Definition of Issue(s) and Grounds of Dispute

This section should be a brief, high-level summary of the issue(s) in dispute, and should not introduce new issues.

In this section the sponsor should include statements, in numbered paragraphs, with the definition of the issue(s) of contention, linking closely with the points of the original decision (attached). For each issue identified, the grounds of the dispute should be provided in numbered paragraphs. The grounds should be cross-referenced to the information filed in the original submission (and/or the response to a Screening Deficiency Notice, Notice of Deficiency, or Notice of Non-compliance). Issues not contested will remain outstanding at the end of the Reconsideration process and will have to be addressed in a refile.