

**NAME OF PRODUCT:**

**CHECKLIST C**

**REEVALUATION REQUEST: New diagnostic agent or new nutritional formula with a generic name already listed**

All the required documents must be included in the assessment request on the date it is filed in order to be considered for review. A written explanation is required for each document missing. Refer to the "[Guidance document for submitting a request to INESSS](#)" for a detailed description of the requested items.

Please note that the required clinical and economic data differ according to the reason for the refusal to list:

- If the reevaluation request concerns a diagnostic agent or a nutritional formula that was refused listing for therapeutic reasons, new clinical data are required. A pharmacoeconomic analysis in which the clinical assumptions are based on these data, and a budget impact analysis are required. In both cases, the analysis can be an update of the previous analysis.
- If the reevaluation request concerns a diagnostic agent or a nutritional formula that was refused listing for economic reasons, no action needs to be taken on the requirements in the clinical section. However, a pharmacoeconomic analysis and a budget impact analysis are required. In both cases, the analysis can be an update of the previous analysis.

ADMINISTRATIVE SECTION	REQUIREMENT	DONE	N/A
1. Cover letter	R		
2. Form entitled "Drug Listing Request"	R		
3. Medical device licence issued by Health Canada	R		
4. Labels	R		
5. Proof of marketing	R		
6. Certificate of availability	R		
7. Authorization to share information	R		
<b>CLINICAL SECTION</b>			
1. Data illustrating the accuracy and exactness of results	R		
2. Product description	R		
<b>ECONOMIC SECTION</b>			
1. Price justification	R		
2. Pharmacoeconomic study	R		
3. Budget impact analysis	R		

**LEGEND:** N/A = Not applicable  
R = Required on the date that the assessment request it is filed