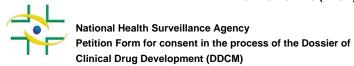
PETITION FORM FOR CONSENT IN PROCESS OF THE DEVELOPMENT DOSSIER MEDICATION CLINIC (DDCM)



Document	Identification

				(For use by the receiving agency)			
Con	npany Data						
1	Requester:	2	City/Sta	ate/Country			
	CNPJ:						
Pro	Product Data						
3	() Synthetic or Semi-synthetic () Phytotherapy () Biological () Radiopharmaceutical () Other: Specify						
4'	4* Product codes under development, if applicable: 5* Active						
	harmaceutical Ingredient or active substance, if applicable: 6* Comme	rcial					
	ame in Brazil, if applicable: 7* Commercial name broad, if applicable: 8 Manufacturer's name: 9 Class						
_	Therapeutic (Anatomical,	Country:					
Т	Therapeutical and Chemical Code) / category: 10 Medicine approved in	Brazil: ÿYes	ÿ No				
	egistration nº11 Medicine approved in the World: ÿYes ÿ						
w	here the medicine is approved:13 The						
р	rocess fits in the exceptions described in §3 of Art.36: () Yes - () No If						
y	es, in which option(s): () National Development () Biological In the cas	se of "non-ne	w" biolo	gical			
13-	medicines, the same intends to be	_	_				
	developed through comparability? () Yes No	() Clinical	Develop	nent Phase I or II			
14	<u> </u>						
1:	5 List of countries in which the clinical development of the investigation	onal drug is i	ntended:				
16	Is there consent(s) in clinical trial(s) process(ies) already filed wit (DDCM)? If so, inform the case number.	th Anvisa to	be linked	to this clinical drug development dossier			
* At	least one field for items 4, 5, 6 and 7 must be filled in.						
	Statement of responsibility						
We assume full civil and criminal responsibility for the information provided here, as well as for the quality of the experimental drug to be used in the clinical development presented, including, where appropriate, its sterility and/or apyrogenicity.							
	Legal representative (Signature and Stamp)			responsible re and Stamp)			