

DATA ITEM DESCRIPTION			Form Approved GSA No. 0706-0188 Exp. Date: Jun 30, 1985	
1. TITLE New Drug Application (NDA)		2. IDENTIFICATION NUMBER DI-MISC-80099		
3. DESCRIPTION/PURPOSE Utilized to inform the Food and Drug Administration that the safety and efficacy of a drug has been demonstrated, and to request approval to market said product.				
4. APPROVAL DATE (YYMMDD) 860110	5. OFFICE OF PRIMARY RESPONSIBILITY (OPR) SGRD-UMP	6a. DTIC REQUIRED X	6b. GIDEP REQUIRED	
7. APPLICATION/INTERRELATIONSHIP 7.1 21 CFR 314 contains the format and content preparation instructions for the data product generated by the specific and discrete task requirement for this data included in the contract.				
8. APPROVAL LIMITATION		9a. APPLICABLE FORMS FD 356H	9b. AMSC NUMBER A3754	
10. PREPARATION INSTRUCTIONS 10.1 Contract. This data item is generated by the contract which contains a specific and discrete work task to develop this data product. 10.2 Preparation shall be in compliance with the requirements cited in 21 Code of Federal Regulations (CFR), Part 314, as constituted at the time of preparation of the New Drug Application (NDA).				