DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG,BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No.0910-0430
Expiration Date: April 30, 2009
See OMB Statement on page 2.

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(1.11.2.1,00.00.0), 1.01.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.				
APPLICANT INFORMATION				
NAME OF APPLICANT		DATE OF SUBMISSION		
Fresenius Kabi Oncology Plc.		30 APRIL 2009		
TELEPHONE NO. (Include Area Code)		FACSIMILE (FAX) Number (Include Area Code)		
+44-1420-477-115 APPLICANT ADDRESS (Number, Street, City, State, Country,	ZID Codo on Moil Codo	+44-1420-477-047		
and U.S. License number if previously issued):	, ZIF Code or Maii Code,	AUTHORIZED U.S AGENT NAME & ADDRESS (Number, Street, City, State, ZIP Code, telephone & FAX number) IF APPLICABLE		
and o.s. Electise number if previously issued).		Gordon Johnston, MS, RPh		
Fresenius Kabi Oncology Plc.		Washington Food and Drug Consultants		
Lion Court, Farnham Road, Bordon		3631, Martins Dairy Circle, Olney, MD 20832, USA		
Hampshire GU35 0NF		Phone number: 240-401-7616, Fax Number: 301-570-7075		
United Kingdom		Email: JohnstoneGJ@aol.com		
PRODUCT DESCRIPTION				
NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OI	R BIOLOGICS LICENSE AP	PLICATION NUMBER (If previously issued)		
ESTABLISHED NAME (e.g., Proper name, USP/USAN name)		PROPRIETARY NAME (trade name) IF ANY		
Topotecan Injection		None		
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME(if any)		CODE NAME (if any)		
(S)-10-[(dimethylamino) methyl]-4-ethyl-4, 9-dihydroxy-1 <i>H</i> -pyrano[3`,4`:6,7] indolizino		None		
[1,2-b]quinoline-3, 14-(4H, 12H)-dione monohydrochloride				
DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:		
Injection	4mg/4ml vial	Intravenous		
(PROPOSED) INDICATION (S) FOR USE:				
Con Attachment 1				
See Attachment 1 APPLICATION DESCRIPTION				
APPLICATION TYPE				
	CDA 21CFR 314 50)	ABBREVIATED NEW DRUG APPLICATION (ANDA, 21CFR 314.94)		
	ez., 21e11(311.00)	ABSECTION STORY BROWN IN THE STORY (ABSECT TO A STORY OF THE STORY OF		
BIOLOGIC	S LICENSE APPLICATION	(BLA, 21 CFR Part 601)		
IF AN NDA,IDENTIFY THE APPROPRIATE TYPE 505 (b)(1) 505(b)(2)				
IF AN ANDA,OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION				
HYCAMTIN® (Topotecan hydrochloride for Injection).				
Sterile Lyophilized Powder GlaxoSmithKline				
Name of Drug (NDA 020-671) Holder of Approved Application Research Triangle Park, NC 27709				
TYPE OF SUBMISSION (check one) ORIGINAL APP	PLICATION AMENI	DMENT TO A PENDING APPLICATION RESUBMISSION		
TYPE OF SUBMISSION (check one) ORIGINAL APPLICATION AMENDMENT TO A PENDING APPLICATION RESUBMISSION				
PRESUBMISSION ANNUAL REPORT ESTABLISHMENT DESCRIPTION SUPPLEMENT EFFICACY SUPPLEMENT				
LABELING SUPPLEMENT CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT OTHER				
IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:				
П П П				
IF A SUPPLEMENT, IDENTIFY THE APPROVED CATEGORY				
REASON FOR SUBMISSION				
Original Abbreviated New Drug Application				
-				
PROPOSED MARKETING STATUS (check one) PRESCRIPTION PRODUCT (Rx)				
NUMBER OF VOLUMES SUBMITTED 1 CD ROM THIS APPLICATION IS PAPER PAPER AND ELECTRONIC ELECTRONIC				
FOTTA DI IGITA ENIT INFORMATION (E. II . 4. biblio . 4. biblio . 4. biblio				
ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of Application.) Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact,				
telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please				
indicate whether the site is ready for inspection or, if not, when it will be ready.				
See Attachments 2 and 3				
Cross References (list related License Application, INDs, NI	OAs, PMAs, 510(k)s, IDEs. I	BMFs, and DMFs referenced in the current application)		
See Attachment 4 and 5				

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