Attachment III

Sample Formats — Form FDA 356h

for

Ammonia N 13 Injection
Fleudioxyglucose F 18 Injection (FDG F 18)
and
Sodium Fluoride F 18 Injection

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, 314 & 601)

Form Approved: OMB No. 0910-0338 Expiration Date: April 30, 2000 See OMB Statement on page 2.

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APPLICATION NUMBER

APPLICANT INFORMATION								
NAME OF APPLICANT			DA	E OF SU	BMISSION			
TELEPHONE NO. (Include Area Code)			FAC	SIMILE (FAX) Numbe	r (Include Area Code)		
APPLICANT ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):				AUTHORIZED U.S. AGENT NAME & ADDRESS (Number, Street, City, State, ZIP Code telephone & FAX number) IF APPLICABLE				
PRODUCT DESCRIPTION								
NEW DRUG OR ANTIBIOTIC APPLICATION NUM	IBER, OR BIOLOG	GICS LICENSE A	PPLICATION	ON NUMB	ER (If previ	ously issued)		
ESTABLISHED NAME (e.g., Proper name, USP/U	SAN name)		PROPRIE	TARY NA	ME (trade n	ame) IF ANY		
Fludeoxyglucose F 18 Injection	,				,	,		
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NA	AME (If any)					CODE NAME (If any)		
DOSAGE FORM: Sterile, Pyrogen Free Injection	STRENGTHS:	mCi/m	L		ROUTE	OF ADMINISTRATION:	Intravenous	
together with myocardial perfusion imaging, reversible loss of systolic function. 3) In positron emission tomography (PET) imaging with foci of epileptic seizures. APPLICATION INFORMATION APPLICATION TYPE (check one) NEW DRUG APPLICATION	ging in patients fo	or the identificat	ion of reg	ons of al	onormal glu	•	iated	
☐ BIOLOG	ICS LICENSE API	PLICATION (21 0	CFR part 6	01)				
IF AN NDA, IDENTIFY THE APPROPRIATE TYPE	505 (b) (1	1)	⊠ 505 (b) (2)		507		
IF AN ANDA, OR AADA, IDENTIFY THE REFERE Name of Drug TYPE OF SUBMISSION		JG PRODUCT TH older of Approved			OR THE SU	BMISSION		
(check one) ☑ ORIGINAL APPLIC ☐ PRESUBMISSION ☐ ANNUAL I	_	_	BLISHMENT	DESCRIPT	TION SUPPLEM	☐ RESUBMISSIC MENT ☐ SUPA AND CONTROLS SUPPLEN	C SUPPLEMENT	₹
REASON FOR SUBMISSION Co	mplete new ap	plication that h	nas nevei	before	been subn	nitted		
PROPOSED MARKETING STATUS (check one)	⊠ PRES	SCRIPTION PRODUC	CT (Rx)		OVER TH	E COUNTER PRODUCT (O	TC)	
NUMBER OF VOLUMES SUBMITTED		THIS APPLICAT	TON IS	×	PAPER	☐ PAPER AND ELECT	RONIC ELECTRON	ΝIC
ESTABLISHMENT INFORMATION Provide locations of all manufacturing, packaging address, contact, telephone number, registration r conducted at the site. Please indicate whether the	number (CFN), DN	MF number, and r	manufactur	ing steps	and/or type			
Cross References (list related License Apapplication)	plications, IND	os, NDAs, PMA	s, 510(k)	s, IDEs,	BMFs, and	I DMFs referenced ir	the current	

FORM FDA 356h (7/97)

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✓	1.	Index					
1	2.	Labeling (check one) Draft Labeling	eling	☐ Final Printed Labeling	g		
✓	3. Summary (21 CFR 314.50(c))						
✓	4.	Chemistry section					
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		C. Methods validation package (e.g. 21 CFR 3	14.50 (e) (2) (l)	, 21 CFR 601.2)			
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*	6.	Human pharmacokinetics and bioavailability se					
	7.	Clinical Microbiology (e.g. 21 CFR 314.50 (d) ((4))				
*	8.	Clinical data section (e.g. 21 CFR 314.50 (d) (s		2)			
*	9.	Safety update report (e.g. 21 CFR 314.50 (d) (-				
*		Statistical section (e.g. 21 CFR 314.50 (d) (6),		,			
*		. Case report tabulations (e.g. 21 CFR 314.50 (f		01.2)			
*	12	. Case report forms (e.g. 21 CFR 314.50 (f) (2),	21 CFR 601.2)				
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✓	14	. A patent certification w ith respect to any paten	t which claims t	he drug (21 U.S.C.355 (b	o) (2) or (j) (2) (A)		
	15	. Establishment description (21 CFR Part 600, ii	f applicable)				
✓		. Debarment certification (FD&C Act 306 (k) (1))					
✓	17	. Field copy certification (21 CFR 314.50(k) (3))					
√	18	. User Fee Cover Sheet (Form FDA 3397)					
✓	19	. OTHER (Specify) See Attached Sheets [* F	Reference to Fe	ederal Register Notice]			
I agree warning request includin	CERTIFICATION I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following: 1. Good manufacturing practice regulations in 21 CFR 210 and 211, 606, and/or 820.						
	,	gical establishment standards in 21 CFR Part 60 ling regulations in 21 CFR 201, 606, 610, 660 ar					
		e case of a prescription drug or biological produc		rug advertising regulation	ns in 21 CFR 202.		
		lations on making changes in application in 21 (4.99, and 601.12.		
	-	llations on Reports in 21 CFR 314.80, 314.81, 6 I, state and Federal environmental impact laws.	00.80 and 600.8	31.			
If this ap	oplic	cation applies to a drug product that FDA has pro			ed Substances Act I agree	e not to market the	
		il the Drug Enforcement Administration makes a			contified to be true and a	ouroto	
The data and information in this submission have been review and, to the best of my knowledge are certified to be true and accurate. Warning: a willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.							
SIGNATI	JRE	OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AN	ND TITLE		DATE	
					T= · · · · · · · · ·		
ADDRES	SS (S	Street, City, State, and ZIP Code)			Telephone Number ()		
instruction informat	Public reporting burden for this collection of information is estimated to average 40 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:						
Paperwo Hubert H 200 Inde	DHHS, Reports Clearance Officer An agency may not conduct or sponsor, and a Paperwork Reduction Project (0910-0338) Hubert H. Humphrey Building, Room 531-H 200 Independence Avenue, S.W. Washington, DC 20201 An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.						

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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

Form Approved: OMB No. 0910-0338 Expiration Date: April 30, 2000 See OMB Statement on page 2.

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PRODUCT DESCRIPTION							
NEW DRUG OR ANTIBIOTIC APPLICATION NUM	BER, OR BIOLOG	ICS LICENSE AP	PLICATION NUM	BER (If prev	iously issued)		
ESTABLISHED NAME (e.g., Proper name, USP/US	SAN name)		PROPRIETARY N	IAME (trade	name) IF ANY		
Sodium Fluoride F 18 Injection							
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NA	AME (If any)				CODE NAME (If any)		
DOSAGE FORM: Sterile, Pyrogen Free Injection	STRENGTHS: _	mCi/mL		ROUTE	OF ADMINISTRATION: Intrav	enous	
APPLICATION INFORMATION APPLICATION TYPE							
(check one) NEW DRUG APPLICATION TYPE	ATION (21 CFR 31	14.50)	ABBREVIATED A	PPLICATION	(ANDA, AADA, 21 CFR 31.94)		
☐ BIOLOGI	CS LICENSE APP	LICATION (21 CI	R part 601)				
IF AN NDA, IDENTIFY THE APPROPRIATE TYPE	505 (b) (1)		505 (b) (2)		507		
IF AN ANDA, OR AADA, IDENTIFY THE REFEREI Name of Drug		G PRODUCT THA der of Approved A		FOR THE SU	JBMISSION		
TYPE OF SUBMISSION (check one) SOURCE ORIGINAL APPLICATION	ATION \square A	AMENDMENT TO A F	PENDING APPLICAT	ION	☐ RESUBMISSION		
□ PRESUBMISSION □ ANNUAL F	_		ISHMENT DESCRIF		_	EMENT	
_	LABELING SUPPLEM	_			AND CONTROLS SUPPLEMENT	☐ OTHER	
	mplete new app						
PROPOSED MARKETING STATUS (check one)	▼ PRESO	CRIPTION PRODUC	Γ (Rx)	□ OVER TH	HE COUNTER PRODUCT (OTC)		
NUMBER OF VOLUMES SUBMITTED		THIS APPLICATI	ON IS	PAPER	☐ PAPER AND ELECTRONIC	☐ ELECTRONIC	
ESTABLISHMENT INFORMATION 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.							
Cross References (list related License Ap application)	plications, INDs	s, NDAs, PMAs	, 510(k)s, IDEs	, BMFs, and	d DMFs referenced in the co	urrent	

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*		Statistical section (e.g. 21 CFR 314.50 (d) (6),		,			
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NAME OF APPLICANT			[DATE OF SUI	BMISSION			
TELEPHONE NO. (Include Area Code)			F	FACSIMILE (I	FAX) Numb	oer (Include Area Code)		
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PRODUCT DESCRIPTION								
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ESTABLISHED NAME (e.g., Proper name, USP/U-	SAN name)		PROP	RIETARY NA	ME (trade	name) IF ANY		
Ammonia N 13 Injection								
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NA	AME (If any)					CODE NAME (If any)		
DOSAGE FORM: Sterile, Pyrogen Free Injection	STRENGTHS: _	mCi/m	nL		ROUTE	E OF ADMINISTRATION: In	travenous	
	(PROPOSED) INDICATION(S) FOR USE: For positron emission tomographic (PET) imaging of the myocardium under rest or pharmacologic stress conditions to evaluate myocardial perfusion in patients with suspected or existing coronary artery disease.							
APPLICATION INFORMATION								
APPLICATION TYPE (check one) NEW DRUG APPLICATION TYPE	ATION (21 CFR 3	14.50)	ABBRI	EVIATED AP	PLICATIO	N (ANDA, AADA, 21 CFR 31.	94)	
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IF AN ANDA, OR AADA, IDENTIFY THE REFERE			HAT IS T	HE BASIS F	OR THE S	UBMISSION		
Name of Drug	Но	lder of Approved	d Applica	tion				
TYPE OF SUBMISSION (check one) Check one) ORIGINAL APPLICATION	ATION	AMENDMENT TO A	A PENDIN	IG APPLICATIO	ON	RESUBMISSION		
☐ PRESUBMISSION ☐ ANNUAL	REPORT	☐ ESTA	BLISHME	NT DESCRIPT	ION SUPPLI	EMENT SUPAC SU	JPPLEMENT	
☐ EFFICACY SUPPLEMENT ☐	LABELING SUPPLE	MENT	☐ CHE	MISTRY MANU	JFACTURIN	IG AND CONTROLS SUPPLEMEN	T DTHER	
REASON FOR SUBMISSION Complete new application that has never before been submitted								
PROPOSED MARKETING STATUS (check one)	▼ PRES	CRIPTION PRODU	JCT (Rx)		OVERT	THE COUNTER PRODUCT (OTC)		
NUMBER OF VOLUMES SUBMITTED	_	THIS APPLICA	TION IS	X	PAPER	☐ PAPER AND ELECTRON	IIC ELECTRONIC	
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