Next Page Export Data Import Data Reset Form

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Food and Drug Administration

## APPLICATION TO MARKET A NEW OR ABBREVIATED NEW DRUG OR BIOLOGIC FOR HUMAN USE

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

Form Approved: OMB No. 0910-0338 Expiration Date: Xxxxxx xx, 20xx See PRA Statement on page 3.

1. Date of Submission (mm/dd/yyyy)

APPLICANT INFORMATION	2. Name of Appli	cant		
3. Telephone Number (Include country code	if applicable and	area code)	4. Facsimile (FAX) N code if applicable a	umber (Include country and area code)
5. Applicant Address				
Address 1 (Street address, P.O. box, con	npany name c/o)			Email Address
Address 2 (Apartment, suite, unit, building	g, floor, etc.)			
City	State/Prov	ince/Region		U.S. License Number if previously issued
Country		ZIP or Pos	stal Code	
6. Authorized U.S. Agent (Required for non-	-U.S. applicants)			
Authorized U.S. Agent Name				Telephone Number (Include area code)
Address 1 (Street address, P.O. box, con	npany name c/o)			
Address 2 (Apartment, suite, unit, building	g, floor, etc.)			FAX Number (Include area code)
City	State			Email Address
ZIP Code				
PRODUCT DESCRIPTION	7. NDA, ANDA, c	r RI A Annli	cation Number	Supplement Number (If applicable)
FRODUCT BESCRIFTION	7. 14071, 7114071, 0	л БЕЛТ фріі	odilon ramber	o. Supplement Number (in applicable)
9. Established Name (e.g., proper name, U.	SP/USAN name)			
10. Proprietary Name (Trade Name) (If any	)			
11. Chemical/Biochemical/Blood Product N	ame (If any)			
12. Dosage Form	13. Strengtl	ns		14. Route of Administration
15A. Proposed Indication for Use		this indicat	ion for a rare disease (	prevalence <200,000 in U.S.)?
				· · · · · · · · · · · · · · · · · · ·
	C		duct have an FDA gnation for this	If yes, provide the Orphan Designation number for this indication:  Continuation Page for #15
			Yes No	
15B. SNOMED CT Indication Disease Term	(Use continuation	n page for e	ach additional indicatio	on and respective coded disease term)
APPLICATION INFORMATION	16. Application T	ype $\square$	New Drug Application	(NDA) Biologics License Application (BLA)
	(Select one)		Abbreviated New Drug	Application (ANDA)
17. If an NDA, identify the type 505(	b)(1) 505(l	b)(2)	18. If a BLA, identify	the type 351(a) 351(k)
19. If a 351(k), identify the biological referen	nce product that is	s the basis f		
Name of Biologic:			Holder of Licensed A	pplication:
20. If an ANDA, or 505(b)(2), identify the lis	ted drug product t	hat is/are th		
Name of Drug:			Application Number of	of Relied Upon Product:
Indicate Patent Certification: P1	☐ P2 ☐ F	23 🗌 1	P4 Section viii	- MOU Statement of no relevant patents

	Previous Page Next Page									
21.	Submission (See instructions) Original Product Correspondence REMS St				Supplement equirements or		-			ual Report Report
22.	Submission Sub-Type  Presubmission  Initial Submission	Amendmen			pplement, iden propriate categ	-		BE [] F	Prior App	roval (PA)
24.	For Originals and all Supplements, is the procombination product (21 CFR 3.2(e)? Ye	s No	Туре	bination Pro (See instru	ctions)	(RFD	) Numl			
	Only Pediatric data? Yes No		nformation? lo		osed Marketing rescription Prod			ct one) Over-The-Cou	unter Pro	duct (OTC)
	Reasons for Submission									
28.	Establishment Information (Full establishment Establishment Name	information	should be p	provided in	the body of the	applica	ition.)			
	Address 1 (Street address, P.O. box, company	name c/o)				Regist	tration	(FEI) Number		
	Address 2 (Apartment, suite, unit, building, floor	,				MF Nu	umber			
	City	State/Provi	nce/Region			Establ	lishme	nt DUNS Num	ber	
	Country		ZIP or Pos							
	Is the establishment new to the application?	Yes	No	What is th	e status of the e	establish Act		? Inactive	With	drawn
	Establishment Contact Information at the site/in Name of Contact for the Establishment  Address 1 (Street address, P.O. box, company)	•				Telephone Number (Include area code)				
	Address 2 (Apartment, suite, unit, building, floor	r, etc.)				FAX N	lumbe	r (Include area	code)	
	City	State/Provi	nce/Region			Email	Addre	SS		
	Country		ZIP or Pos	tal Code						
	Manufacturing Steps and/or Type of Testing					for i			s N	o 🗌 N/A
								Continuation I		
29.	Cross References (List related BLAs, INDs, N	DAs, PMAs,	, 510(k)s, I⊡	DEs, BMFs,	MAFs, and DN	1Fs refe	erence	d in the curren	t applica	Contin. Page for #28
30.	This application contains the following items (	Select all the	at apply)							
	1. Index 2. Labeling (Select one	): Dra	ft Labeling	Final I	Printed Labeling	9		3. Summary (2	21 CFR 3	14.50 (c))
	B. Samples	(21 CFR 31	4.50 (e)(1);	21 CFR 60	mation (e.g., 21 1.2 (a)) (Submit 14.50(e)(2)(i); 2	t only up	on FD	DA's request)	601.2)	
	5. Nonclinical pharmacology and toxicolog (e.g., 21 CFR 314.50(d)(2); 21 CFR 60				man pharmaco g., 21 CFR 314			•	ection	
	7. Clinical microbiology section (e.g., 21 C	CFR 314.50(c	d)(4))	8. Cli	nical data section	on (e.g.,	21 CF	. , , ,	,-	
								Item 31 c	ontinued	on page 3

	Previous Page Next Page	9								
31	. This application contains the following it	ems (Continued;	select all tha	at app	ly)					
	9. Safety update report (e.g., 21 CF 21 CFR 601.2)	R 314.50(d)(5)(vi)	(b);		10. S	tatis	tical section	on (e.g., 21 CFR	314.50(d)(6); 21	CFR 601.2)
	11. Case report tabulations (e.g., 20 21 CFR 601.2)	1 CFR 314.50(f)(1)	;		12. C	ase	report forr	ms (e.g., 21 CFR	? 314.50 (f)(2); 21	CFR 601.2)
	13. Patent information on any pater biologic (21 U.S.C. 355(b) or (c)		rug/					ation with respect 1 U.S.C. 355 (b)	t to any patent th	nat claims the
	15. Establishment description (21 C)	FR Part 600, if ap	olicable)		16. D	ebar	ment cert	ification (FD&C A	Act 306 (k)(1))	
	17. Field copy certification (21 CFR	314.50 (l)(3))						,	Form FDA 3397, ( 92, or MDUFA Fo	
	19. Financial Disclosure Information	(21 CFR Part 54)		•						
	20. Other (Specify):									
If the	gree to update this application with new samings, precautions, or adverse reactions quested by FDA. If this application is approbation, but not limited to, the following:  1. Good manufacturing practice reg 2. Biological establishment standard 3. Labeling regulations in 21 CFR P 4. In the case of a prescription drug 5. Regulations on making changes 6. Regulations on Reports in 21 CF 7. Local, state, and Federal environ this application applies to a drug product to product until the Drug Enforcement Admite data and information in this submission arning: A willfully false statement is a crin	in the draft labeling oved, I agree to consider the constant of the constant o	ng. I agree to comply with a R Parts 210, 600.  R 600.  R 660, and/ouct, prescrip D&C Act sec 600.80, and sec sec for schaffnal schewed and, to to comply with a final schewed and, to to second parts of the complex of	to subsall app 211 of or 809 otion oction of d 600 meduling the be	mit sa blicable or appl 0. drug a 506A, 81. ng und g decisest of r	fety e lav licab dver 21 C der to sion. my k	update rews and regulate regulate tising regulate CFR 314.7	ports as provide gulations that ap ions, Parts 606, ulations in 21 CF 1, 314.72, 314.9	and/or 820.  FR Part 202.  TR 97, 314.99, and 6	on or as applications, 601.12.
32	. Typed Name and Title of Applicant's Re	sponsible Official							33. Date (mm.	/dd/yyyy)
34	. Telephone Number (Include country code if applicable and area code)	35. FAX Number applicable an			code ii	f	36. Emai	I Address		
37	. Address of Applicant's Responsible Offi	cial								
Г	Address 1 (Street address, P.O. box, con	npany name c/o)								
	Address 2 (Apartment, suite, unit, building	g, floor, etc.)						_		
		,								
	City	State/Prov	ince/Region							
	Country	<u> </u>	ZIP or Pos	tal Co	de			-		
38	. Signature of Applicant's Responsible Of Other Authorized Official	ficial or	Sign	39. (	Counte	ersig	gnature of	Authorized U.S.	Agent	Sign
	The information  The burden time for this collection of information including the time to review instructions, sear data needed and complete and review the colthis burden estimate or any other aspect of for reducing this burden to the address to the "An agency may not conduct or sponsor, and collection of information unless it displays a decollection of information unless it displays a decollection of information unless it displays a decollection."	ch existing data sou lection of informatio this information coll right:	rerage 24 hources, gather on. Send comection, include	urs per and m nments ding si	respo aintair regar uggest	nse, n the ding	D F C P P	repartment of Hea ood and Drug Adi office of Operation aperwork Reduct PRAStaff@fda.hhs	alth and Human Se ministration is ion Act (PRA) Sta	ff D FORM
		,					•			

Remove Continuation Page Return to	o Form
FIRST CONTINUATION PAGE FOR ITEM 15	5 – Proposed Indication for Use
Please fill out as many sets of answers as neede	ed, completing all elements within each set that you start.
15A. Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)?
	Does this product have an FDA Orphan Designation for this indication?  Yes No  If yes, provide the Orphan Designation number for this indication:
15B. SNOMED CT Indication Disease Term	
15A. Proposed Indication for Use	
To a Proposed management ese	Is this indication for a rare disease (prevalence <200,000 in U.S.)?
	Does this product have an FDA Orphan Designation for this indication?  Yes No  If yes, provide the Orphan Designation number for this indication:
15B. SNOMED CT Indication Disease Term	
15A. Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)?
	Does this product have an FDA Orphan Designation for this indication?  Yes No  If yes, provide the Orphan Designation number for this indication:
15B. SNOMED CT Indication Disease Term	
15A. Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)?
	Does this product have an FDA Orphan Designation for this indication?  Yes No  If yes, provide the Orphan Designation number for this indication:
15B. SNOMED CT Indication Disease Term	
15A. Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)?
	Does this product have an FDA Orphan Designation for this indication?  If yes, provide the Orphan Designation number for this indication:
15B. SNOMED CT Indication Disease Term	
15A Proposed Indication for Lice	
15A. Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)?
	Does this product have an FDA Orphan Designation for this indication?  If yes, provide the Orphan Designation number for this indication:
15B. SNOMED CT Indication Disease Term	☐ Yes ☐ No ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

**Remove Continuation Page** 

Return to Form

Add Second Continuation Page for #15

ECOND CONTINUATION PAGE FOR ITE	ded, completing all elements within each set that you start.	
5A. Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)?	
	Does this product have an FDA Orphan Designation for this indication?  Yes  No  No  No  No  No  No  No  No  No  N	
5B. SNOMED CT Indication Disease Term		
5A. Proposed Indication for Use		
DA. Proposed indication for ose	Is this indication for a rare disease (prevalence <200,000 in U.S.)?	
	Does this product have an FDA Orphan Designation for this indication?  Yes No  If yes, provide the Orphan Designation number for this indication:	
5B. SNOMED CT Indication Disease Term		
5A. Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)?	
	Does this product have an FDA Orphan Designation for this indication?  Yes No	
5B. SNOMED CT Indication Disease Term		
5A. Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)?	
	Does this product have an FDA Orphan Designation for this indication?  Yes No  If yes, provide the Orphan Designation number for this indication:	
5B. SNOMED CT Indication Disease Term		
5A. Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)?	I
	Does this product have an FDA Orphan Designation for this indication?  Yes No  If yes, provide the Orphan Designation number for this indication:	
5B. SNOMED CT Indication Disease Term		
EA Dropped Indication for U.S.		
5A. Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)?	l
	Does this product have an FDA Orphan Designation for this indication?  If yes, provide the Orphan Designation number for this indication:	
5B. SNOMED CT Indication Disease Term	Yes No	

Remove Continuation Page

Remove Continuation Page Return to	Form			
FIRST CONTINUATION PAGE FOR ITEM 27	– Establisi	hment Info	ormation	Provide information for additional establishments below, as needed.
Establishment Name				
Address 1 (Street address, P.O. box, company in	name c/o)			Registration (FEI) Number
Address 2 (Apartment, suite, unit, building, floor	; etc.)			MF Number
City	State/Provi	ince/Region	1	
Country		ZIP or Pos	stal Code	Establishment DUNS Number
Is the establishment new to the application?			What is the status of the	establishment?
	Yes	No	Pending	Active Inactive Withdrawn
Establishment Contact Information at the site/f	acility			
Name of Contact for the Establishment				Telephone Number (Include area code)
Address 1 (Street address, P.O. box, company	name c/o)			EAVAN I (I I I I I I I I I I I I I I I I I I
Address 2 (Apartment, suite, unit, building, floor	; etc.)			FAX Number (Include area code)
City	State/Provi	ince/Region	1	Email Address
Country		ZIP or Pos	stal Code	
Manufacturing Steps and/or Type of Testing				Is the site ready Yes No N/A for inspection?  If No, when will site be ready? (mm/dd/yyyy)
Establishment Name				
Address 1 (Street address, P.O. box, company of	name c/o)			Registration (FEI) Number
Address 2 (Apartment, suite, unit, building, floor	; etc.)			MF Number
City	State/Provi	ince/Region	1	
Country		ZIP or Pos	stal Code	Establishment DUNS Number
Is the establishment new to the application?	Yes	No	What is the status of the e	establishment?  Active Inactive Withdrawn
Establishment Contact Information at the site/f		-		
Name of Contact for the Establishment				Telephone Number (Include area code)

Address 1 (Street address, P.O. box, company name c/o) FAX Number (Include area code) Address 2 (Apartment, suite, unit, building, floor, etc.) City State/Province/Region Email Address ZIP or Postal Code Country Manufacturing Steps and/or Type of Testing Is the site ready Yes No N/A for inspection? If No, when will site be ready? (mm/dd/yyyy) Add Second Continuation Page for #27 Page X of X **Remove Continuation Page** Return to Form

FORM FDA 356h (02/18)

Remove Continuation Page Return to	Form	
SECOND CONTINUATION PAGE FOR ITEM	27 – Establishment Information	Provide information for additional establishments below, as needed.
Establishment Name		
Address 1 (Street address, P.O. box, company	name c/o)	Registration (FEI) Number
Address 2 (Apartment, suite, unit, building, floor	r, etc.)	MF Number
City	State/Province/Region	
Country	ZIP or Postal Code	Establishment DUNS Number
Is the establishment new to the application?	Yes No What is the status of th Pending	e establishment? Active Inactive Withdrawn
Establishment Contact Information at the site/	facility	
Name of Contact for the Establishment		Telephone Number (Include area code)
Address 1 (Street address, P.O. box, company	name c/o)	FAVALuaria and displayed a secondary
Address 2 (Apartment, suite, unit, building, floo	r, etc.)	FAX Number (Include area code)
City	State/Province/Region	Email Address
Country	ZIP or Postal Code	
Manufacturing Steps and/or Type of Testing		Is the site ready Yes No N/A for inspection?  If No, when will site be ready? (mm/dd/yyyy)
Establishment Name		
Address 1 (Street address, P.O. box, company	name c/o)	Registration (FEI) Number
Address 2 (Apartment, suite, unit, building, floo	r, etc.)	MF Number
City	State/Province/Region	
Country	ZIP or Postal Code	Establishment DUNS Number
Is the establishment new to the application?	What is the status of th  ☐ Yes ☐ No ☐ Pending	e establishment?
Establishment Contact Information at the site/	facility	
Name of Contact for the Establishment		Telephone Number (Include area code)

Address 1 (Street address, P.O. box, company name c/o) FAX Number (Include area code) Address 2 (Apartment, suite, unit, building, floor, etc.) City State/Province/Region **Email Address** ZIP or Postal Code Country Manufacturing Steps and/or Type of Testing Is the site ready Yes No N/A for inspection? If No, when will site be ready? (mm/dd/yyyy) Add Third Continuation Page for #27

FORM FDA 356h (02/18) Page X of X **Remove Continuation Page** Return to Form

**Remove Continuation Page** Return to Form Provide information for additional THIRD CONTINUATION PAGE FOR ITEM 27 – Establishment Information establishments below, as needed.

Establishment Name							
Address 1 (Street address, P.O. box, company	name c/o)				Registration	(FEI) Number	
Address 2 (Apartment, suite, unit, building, floor	r, etc.)				MF Number		
City	State/Prov	ince/Region					
Country		ZIP or Pos	tal Code		Establishmer	nt DUNS Num	ber
Is the establishment new to the application?	Yes	No	What is the	e status of the o	establishment? Active	Inactive	Withdrawn
Establishment Contact Information at the site/	acility						
Name of Contact for the Establishment	•				Telephone N	umber (Include	e area code)
Address 1 (Street address, P.O. box, company	name c/o)				FAX Number	(Include area	code)
Address 2 (Apartment, suite, unit, building, floor	; etc.)				T / OK TRUITISET	(moidae area	0000)
City	State/Prov	ince/Region			Email Addres	SS	
Country		ZIP or Pos	stal Code				
Manufacturing Steps and/or Type of Testing					Is the site of for inspecting If No, when ready? (mi	ion? ion? ion?	s No N/A
Establishment Name							
Address 1 (Street address, P.O. box, company	name c/o)				Registration	(FEI) Number	
Address 2 (Apartment, suite, unit, building, floor	r, etc.)				MF Number		
City	State/Prov	ince/Region					
Country		ZIP or Pos	stal Code		Establishment DUNS Number		
Is the establishment new to the application?		_	What is the	e status of the	□ establishment?		
	Yes	No		Pending	Active	Inactive	Withdrawn
Establishment Contact Information at the site/f	acility						
Name of Contact for the Establishment					Telephone N	umber (Include	e area code)
Address 1 (Street address, P.O. box, company	name c/o)				FAVAL		
Address 2 (Apartment, suite, unit, building, floor	r, etc.)				FAX Number	(Include area	code)
City	State/Prov	ince/Region			Email Addres	SS	
Country		ZIP or Pos	stal Code				
Manufacturing Steps and/or Type of Testing					ready? (mi	ion? Te	s No N/A

FORM FDA 356h (02/18)

Page X of X

**Remove Continuation Page** 

OURTH CONTINUATION	PAGE FOR ITEM 27 – Esta	blishment Information	Provide information for additional establishments below, as needed.
Establishment Name			establishments below, as needed.
Address 1 (Street address,	P.O. box, company name c/o)		Registration (FEI) Number
Address 2 (Apartment, suit	e, unit, building, floor, etc.)		MF Number
City	State/Pro	vince/Region	Fatablishes and DUNG North an
Country		ZIP or Postal Code	Establishment DUNS Number
Is the establishment new to	the application?	What is the status of th	
Establishment Contact Info	ormation at the site/facility		
Name of Contact for the Es	stablishment		Telephone Number (Include area code)
Address 1 (Street address,	P.O. box, company name c/o)		
Address 2 (Apartment, suit	e, unit, building, floor, etc.)		FAX Number (Include area code)
City	State/Pro	ovince/Region	Email Address
Country		ZIP or Postal Code	
Manufacturing Steps and/o	r Type of Testing		Is the site ready Yes No N/A for inspection?  If No, when will site be ready? (mm/dd/yyyy)
Establishment Name			
Address 1 (Street address,	P.O. box, company name c/o)		Registration (FEI) Number
Address 2 (Apartment, suit	e, unit, building, floor, etc.)		MF Number
City	State/Pro	ovince/Region	
Country		ZIP or Postal Code	Establishment DUNS Number
Is the establishment new to	the application?	What is the status of the No Pending	
Establishment Contact Info	ormation at the site/facility		
Name of Contact for the Es	tablishment		Telephone Number (Include area code)
Address 1 (Street address,	P.O. box, company name c/o)		
Address 2 (Anartment suit			FAX Number (Include area code)

City State/Province/Region Email Address Country ZIP or Postal Code Is the site ready for inspection? Manufacturing Steps and/or Type of Testing Yes No N/A If No, when will site be ready? (mm/dd/yyyy) Add Fifth Continuation Page for #27

FORM FDA 356h (02/18) Page X of X **Remove Continuation Page** 

Remove Continuation Page Return t	to Form			
IFTH CONTINUATION PAGE FOR ITEM 2	7 – Establis	hment Info	ormation	Provide information for additional establishments below, as needed.
Establishment Name				
Address 1 (Street address, P.O. box, compan	y name c/o)			Registration (FEI) Number
Address 2 (Apartment, suite, unit, building, flo	oor, etc.)			MF Number
City	State/Prov	ince/Region	ı	
Country		ZIP or Pos	stal Code	Establishment DUNS Number
Is the establishment new to the application?	Yes	No	What is the status of the Pending	establishment? Active Inactive Withdrawn
Establishment Contact Information at the site	e/facility			
Name of Contact for the Establishment				Telephone Number (Include area code)
Address 1 (Street address, P.O. box, compan	y name c/o)			
Address 2 (Apartment, suite, unit, building, flo	oor, etc.)			FAX Number (Include area code)
City	State/Prov	ince/Region		Email Address
Country		ZIP or Pos	stal Code	
Manufacturing Steps and/or Type of Testing				Is the site ready Yes No N/A for inspection?  If No, when will site be ready? (mm/dd/yyyy)
Establishment Name				
Address 1 (Street address, P.O. box, company	y name c/o)			Registration (FEI) Number
Address 2 (Apartment, suite, unit, building, flo	or, etc.)			MF Number
City	State/Prov	ince/Region		
Country		ZIP or Pos	stal Code	Establishment DUNS Number
Is the establishment new to the application?	Yes	No	What is the status of the Pending	establishment? Active Inactive Withdrawn
Establishment Contact Information at the site	e/facility		-	
Name of Contact for the Establishment	•			Telephone Number (Include area code)
Address 1 (Street address, P.O. box, compan	y name c/o)			

FAX Number (Include area code) Address 2 (Apartment, suite, unit, building, floor, etc.) State/Province/Region City Email Address ZIP or Postal Code Country Manufacturing Steps and/or Type of Testing Is the site ready ☐ Yes ☐ No ☐ N/A for inspection? If No, when will site be ready? (mm/dd/yyyy) Add Sixth Continuation Page for #27

FORM FDA 356h (02/18) Page X of X **Remove Continuation Page** Return to Form

(TH CONTINUATION PAGE FOR I	TEM 27 – Establis	hment Inf	ormation	Provide information for additional establishments below, as needed.
Establishment Name				
Address 1 (Street address, P.O. box, o	company name c/o)			Registration (FEI) Number
Address 2 (Apartment, suite, unit, build	ding, floor, etc.)			MF Number
City	State/Prov	rince/Regior	1	
Country		ZIP or Po	stal Code	Establishment DUNS Number
Is the establishment new to the applica	ation?	No	What is the status of the Pending	establishment? Active Inactive Withdrawn
Establishment Contact Information at	the site/facility			
Name of Contact for the Establishmen	<u> </u>			Telephone Number (Include area code)
Address 1 (Street address, P.O. box, o	company name c/o)			
Address 2 (Apartment, suite, unit, build	ding, floor, etc.)			FAX Number (Include area code)
City	State/Prov	rince/Regior	1	Email Address
Country		ZIP or Po	stal Code	
Manufacturing Steps and/or Type of Te	esting			Is the site ready Yes No N/A for inspection?  If No, when will site be ready? (mm/dd/yyyy)
Establishment Name				
Address 1 (Street address, P.O. box, o	company name c/o)			Registration (FEI) Number
Address 2 (Apartment, suite, unit, build	ding, floor, etc.)			MF Number
City	State/Prov	ince/Region	1	
Country		ZIP or Po	stal Code	Establishment DUNS Number
Is the establishment new to the applica	ation?	No	What is the status of the Pending	establishment?  Active Inactive Withdrawn
Establishment Contact Information at	the site/facility			
Name of Contact for the Establishmen				Telephone Number (Include area code)
Address 1 (Street address, P.O. box, o	company name c/o)			
Address 2 (Apartment, suite, unit, build	ding, floor, etc.)			FAX Number (Include area code)

City State/Province/Region Email Address ZIP or Postal Code Country Is the site ready for inspection? Manufacturing Steps and/or Type of Testing Yes No N/A If No, when will site be ready? (mm/dd/yyyy) Add Seventh Continuation Page for #27

FORM FDA 356h (02/18) Page X of X **Remove Continuation Page** Return to Form

**Remove Continuation Page** Return to Form Provide information for additional SEVENTH CONTINUATION PAGE FOR ITEM 27 – Establishment Information establishments below, as needed.

Address 1 (Street address, P.O. box, company	name c/o)				Registration	(FEI) Number	
Address 2 (Apartment, suite, unit, building, floo	r, etc.)				MF Number		
City	State/Pro	vince/Region	1				
Country		ZIP or Pos	stal Code		Establishme	nt DUNS Num	ber
Is the establishment new to the application?			What is the		□ establishment?	?	
L	Yes	No		Pending	Active	Inactive	Withdrawn
Establishment Contact Information at the site/	facility						
Name of Contact for the Establishment					Telephone N	umber (Includ	e area code)
Address 1 (Street address, P.O. box, company	name c/o)				EAY Number	r (Include area	a code)
Address 2 (Apartment, suite, unit, building, floo	r, etc.)				FAX Nullibei	(IIICIUUE area	(code)
City	State/Pro	vince/Region	1		Email Addres	SS	
Country		ZIP or Pos	stal Code				
Manufacturing Steps and/or Type of Testing							s No N/A
Establishment Name							
Address 1 (Street address, P.O. box, company	name c/o)				Registration	(FEI) Number	
Address 1 (Street address, P.O. box, company  Address 2 (Apartment, suite, unit, building, floo					Registration  MF Number	(FEI) Number	
	r, etc.)	vince/Regior	1			(FEI) Number	
Address 2 (Apartment, suite, unit, building, floo	r, etc.)	vince/Region			MF Number	(FEI) Number	
Address 2 (Apartment, suite, unit, building, floo	r, etc.)		stal Code	status of the	MF Number	nt DUNS Num	
Address 2 (Apartment, suite, unit, building, floo  City  Country	r, etc.)		stal Code	status of the	MF Number Establishme	nt DUNS Num	
Address 2 (Apartment, suite, unit, building, floo  City  Country	r, etc.) State/Pro	ZIP or Pos	stal Code	_	MF Number  Establishment	nt DUNS Num	ber
Address 2 (Apartment, suite, unit, building, floo  City  Country  Is the establishment new to the application?	r, etc.) State/Pro	ZIP or Pos	stal Code	_	MF Number  Establishmenta  establishmenta  Active	nt DUNS Num	ber  Withdrawn
Address 2 (Apartment, suite, unit, building, floo  City  Country  Is the establishment new to the application?  Establishment Contact Information at the site/	r, etc.)  State/Pro  Yes	ZIP or Pos	stal Code	_	MF Number  Establishment?  Active  Telephone N	nt DUNS Num  Inactive	ber  Withdrawn  e area code)
Address 2 (Apartment, suite, unit, building, floo  City  Country  Is the establishment new to the application?  Establishment Contact Information at the site/  Name of Contact for the Establishment	r, etc.)  State/Pro  Yes  facility  name c/o)	ZIP or Pos	stal Code	_	MF Number  Establishment?  Active  Telephone N	nt DUNS Num ? Inactive	ber  Withdrawn  e area code)
Address 2 (Apartment, suite, unit, building, floo  City  Country  Is the establishment new to the application?  Establishment Contact Information at the site/ Name of Contact for the Establishment  Address 1 (Street address, P.O. box, company	r, etc.)  State/Pro  Yes  facility  name c/o)  r, etc.)	ZIP or Pos	What is the	_	MF Number  Establishment?  Active  Telephone N	nt DUNS Num  Inactive  Iumber (Includ	ber  Withdrawn  e area code)
Address 2 (Apartment, suite, unit, building, floo  City  Country  Is the establishment new to the application?  Establishment Contact Information at the site/ Name of Contact for the Establishment  Address 1 (Street address, P.O. box, company  Address 2 (Apartment, suite, unit, building, floo	r, etc.)  State/Pro  Yes  facility  name c/o)  r, etc.)	ZIP or Pos	What is the	_	MF Number  Establishment? Active  Telephone N  FAX Number	nt DUNS Num  Inactive  Iumber (Includ	ber  Withdrawn  e area code)

FORM FDA 356h (02/18)

Page X of X

**Remove Continuation Page** Return to Form Provide information for additional EIGHTH CONTINUATION PAGE FOR ITEM 27 - Establishment Information establishments below, as needed. Establishment Name Address 1 (Street address, P.O. box, company name c/o) Registration (FEI) Number Address 2 (Apartment, suite, unit, building, floor, etc.) MF Number City State/Province/Region Establishment DUNS Number Country ZIP or Postal Code Is the establishment new to the application? What is the status of the establishment? Yes No Pending Active Inactive Withdrawn Establishment Contact Information at the site/facility Name of Contact for the Establishment Telephone Number (Include area code) Address 1 (Street address, P.O. box, company name c/o) FAX Number (Include area code) Address 2 (Apartment, suite, unit, building, floor, etc.) City State/Province/Region Email Address ZIP or Postal Code Country Is the site ready Manufacturing Steps and/or Type of Testing Yes No N/A for inspection? If No, when will site be ready? (mm/dd/yyyy) Establishment Name Address 1 (Street address, P.O. box, company name c/o) Registration (FEI) Number Address 2 (Apartment, suite, unit, building, floor, etc.) MF Number City State/Province/Region Establishment DUNS Number ZIP or Postal Code Country What is the status of the establishment? Is the establishment new to the application? Yes No Pending Active Inactive Withdrawn Establishment Contact Information at the site/facility Name of Contact for the Establishment Telephone Number (Include area code)

Address 1 (Street address, P.O. box, company name c/o) FAX Number (Include area code) Address 2 (Apartment, suite, unit, building, floor, etc.) City State/Province/Region **Email Address** ZIP or Postal Code Country Is the site ready Manufacturing Steps and/or Type of Testing Yes No N/A for inspection? If No, when will site be ready? (mm/dd/yyyy) Add Ninth Continuation Page for #27

FORM FDA 356h (02/18) Page X of X

**Remove Continuation Page** Return to Form Provide information for additional NINTH CONTINUATION PAGE FOR ITEM 27 – Establishment Information establishments below, as needed.

Address 1 (Street address, P.O. box, company name c/o)					Registration (FEI) Number			
Address 2 (Apartment, suite, unit, building, floo	r, etc.)				MF Number			
ity State/Province/Region								
Country ZIP or Postal Code					Establishment DUNS Number			
Is the establishment new to the application?	Yes	No	What is the	status of the	establishment?	Inactive	Withdrawn	
Establishment Contact Information at the site/								
Name of Contact for the Establishment	raciiity				Telephone N	umber (Includ	e area code)	
Address 1 (Street address, P.O. box, company name c/o)					FAX Number (Include area code)			
Address 2 (Apartment, suite, unit, building, floo	r, etc.)				FAX Nullibel	(Include area	code)	
City	State/Province/Region				Email Address			
Country		ZIP or Pos	stal Code					
Manufacturing Steps and/or Type of Testing					Is the site ready Yes No N/A for inspection?  If No, when will site be ready? (mm/dd/yyyy)			
Establishment Name								
Address 1 (Street address, P.O. box, company	name c/o)				Registration	(FEI) Number		
Address 1 (Street address, P.O. box, company  Address 2 (Apartment, suite, unit, building, floor					Registration  MF Number	(FEI) Number		
	r, etc.)	vince/Region	1			(FEI) Number		
Address 2 (Apartment, suite, unit, building, floo	r, etc.)	vince/Region			MF Number	(FEI) Number		
Address 2 (Apartment, suite, unit, building, floo	r, etc.) State/Pro	ZIP or Pos	stal Code	_	MF Number  Establishment?	nt DUNS Num	ber	
Address 2 (Apartment, suite, unit, building, flood City  Country  Is the establishment new to the application?	r, etc.) State/Pro		stal Code	status of the	MF Number Establishmet	nt DUNS Num		
Address 2 (Apartment, suite, unit, building, floodity  Country  Is the establishment new to the application?  Establishment Contact Information at the site/	r, etc.) State/Pro	ZIP or Pos	stal Code	_	MF Number  Establishment?  Active	nt DUNS Num	ber  Withdrawn	
Address 2 (Apartment, suite, unit, building, floodity  Country  Is the establishment new to the application?  Establishment Contact Information at the site/Nume of Contact for the Establishment	r, etc.)  State/Pro  Yes	ZIP or Pos	stal Code	_	MF Number  Establishment?  Active	nt DUNS Num	ber  Withdrawn	
Address 2 (Apartment, suite, unit, building, flood City  Country  Is the establishment new to the application?  Establishment Contact Information at the site/N Name of Contact for the Establishment  Address 1 (Street address, P.O. box, company)	r, etc.)  State/Pro  Yes  facility  name c/o)	ZIP or Pos	stal Code	_	MF Number  Establishment?  Active  Telephone N	nt DUNS Num	ber  Withdrawn  e area code)	
Address 2 (Apartment, suite, unit, building, flood City  Country  Is the establishment new to the application?  Establishment Contact Information at the site/Name of Contact for the Establishment  Address 1 (Street address, P.O. box, company  Address 2 (Apartment, suite, unit, building, flood	r, etc.)  State/Pro  Yes  facility  name c/o)  r, etc.)	ZIP or Pos	What is the	_	MF Number  Establishment?  Active  Telephone N	nt DUNS Num  Inactive  umber (Includ	ber  Withdrawn  e area code)	
Address 2 (Apartment, suite, unit, building, flood City  Country  Is the establishment new to the application?  Establishment Contact Information at the site/N Name of Contact for the Establishment  Address 1 (Street address, P.O. box, company)	r, etc.)  State/Pro  Yes  facility  name c/o)  r, etc.)	ZIP or Pos	What is the	_	MF Number  Establishment?  Active  Telephone N	Inactive umber (Includ	ber  Withdrawn  e area code)	
Address 2 (Apartment, suite, unit, building, flood City  Country  Is the establishment new to the application?  Establishment Contact Information at the site/Name of Contact for the Establishment  Address 1 (Street address, P.O. box, company  Address 2 (Apartment, suite, unit, building, flood	r, etc.)  State/Pro  Yes  facility  name c/o)  r, etc.)	ZIP or Pos	What is the	_	MF Number  Establishment?  Active  Telephone N  FAX Number	Inactive umber (Includ	ber  Withdrawn  e area code)	

FORM FDA 356h (02/18)

Page X of X

**Remove Continuation Page** 

**Remove Continuation Page** Return to Form Provide information for additional TENTH CONTINUATION PAGE FOR ITEM 27 – Establishment Information establishments below, as needed. Establishment Name Address 1 (Street address, P.O. box, company name c/o) Registration (FEI) Number Address 2 (Apartment, suite, unit, building, floor, etc.) MF Number City State/Province/Region Establishment DUNS Number Country ZIP or Postal Code Is the establishment new to the application? What is the status of the establishment? Yes No Pending Active Inactive Withdrawn Establishment Contact Information at the site/facility Name of Contact for the Establishment Telephone Number (Include area code) Address 1 (Street address, P.O. box, company name c/o) FAX Number (Include area code) Address 2 (Apartment, suite, unit, building, floor, etc.) City State/Province/Region Email Address ZIP or Postal Code Country Is the site ready Manufacturing Steps and/or Type of Testing Yes No N/A for inspection? If No, when will site be ready? (mm/dd/yyyy) Establishment Name Address 1 (Street address, P.O. box, company name c/o) Registration (FEI) Number Address 2 (Apartment, suite, unit, building, floor, etc.) MF Number City State/Province/Region Establishment DUNS Number ZIP or Postal Code Country What is the status of the establishment? Is the establishment new to the application? Yes No Pending Active Inactive Withdrawn Establishment Contact Information at the site/facility Name of Contact for the Establishment Telephone Number (Include area code) Address 1 (Street address, P.O. box, company name c/o) FAX Number (Include area code) Address 2 (Apartment, suite, unit, building, floor, etc.) City State/Province/Region

**Email Address** ZIP or Postal Code Country Manufacturing Steps and/or Type of Testing Is the site ready Yes No N/A for inspection? If No, when will site be ready? (mm/dd/yyyy)

FORM FDA 356h (02/18)

Page X of X

**Remove Continuation Page** 

	Remove Continuation Page	Return to Form			
	ITINUATION PAGE FOR ITE				
Continue your answer in the space below.					
	Remove Continuation Page	Return to Form			