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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	e 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, cor	mpany name c/o)			Email Address
Address 2 (Apartment, suite, unit, buildir	g, floor, etc.)			
City	State/Prov	/ince/Region		U.S. License Number if previously issued
Country	<u> </u>	ZIP or Pos	stal Code	
6. Authorized U.S. Agent (Required for non	-U.S. applicants)			11
Authorized U.S. Agent Name				Telephone Number (Include area code)
Address 1 (Street address, P.O. box, cor	mpany name c/o)			
Address 2 (Apartment, suite, unit, buildir	g, floor, etc.)			FAX Number (Include area code)
City	State			Email Address
ZIP Code				
PRODUCT DESCRIPTION	7. NDA, ANDA, o	or BLA Appli	ration Number	Supplement Number (If applicable)
PRODUCT DESCRIPTION	7.1457,74457,	л БЕЛЛЕРІІ	odion ramber	o. Supplement Number (in applicable)
9. Established Name (e.g., proper name, U	ISP/USAN name)			
10. Proprietary Name (Trade Name) (If any	<i>'</i>)			
11. Chemical/Biochemical/Blood Product N	lame (If any)			
12. Dosage Form	13. Strengt	hs		14. Route of Administration
15A. Proposed Indication for Use		s 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	ı (Use continuatio	n page for e	ach additional indication	on and respective coded disease term)
APPLICATION INFORMATION	16. Application T (Select one)		New Drug Application Abbreviated New Drug	
17. If an NDA, identify the type 505	(b)(1) 505(b)(2)	18. If a BLA, identify	the type 351(a) 351(k)
19. If a 351(k), identify the biological refere	nce product that is	s the basis f	or the submission.	
Name of Biologic:			Holder of Licensed A	pplication:
20. If an ANDA, or 505(b)(2), identify the list	sted drug product	that is/are th	e basis for the submis	esion.
Name of Drug:			Application Number of	of Relied Upon Product:
Indicate Patent Certification: P1	☐ P2 ☐ I	P3 🗌 I	P4 Section viii	- MOU Statement of no relevant patents

Previous Page Next Page									
21. Submission (See instructions) Original Product Correspondence REMS S	Labeling S upplement Other (S			Supplement quirements or (Supplement Periodi	Annual	•
22. Submission Sub-Type Presubmission Initial Submission	Amendmen Resubmiss			oplement, iden propriate categ	-		BE	rior Approv	al (PA)
24. For Originals and all Supplements, is the procombination product (21 CFR 3.2(e)? Yes	es 🗌 No	Туре	bination Pro (See instru	ctions)	(RFD) Numb			
25. Does the submission contain: Only Pediatric data? Yes No		nformation? lo		sed Marketing escription Prod		(Select	tone) Over-The-Cou	nter Produc	et (OTC)
27. Reasons for Submission									
28. Establishment Information (Full establishment Establishment Name	t information	should be p	provided in t	he body of the	applica	tion.)			
Address 1 (Street address, P.O. box, company	name c/o)				Regist	tration ((FEI) Number		
Address 2 (Apartment, suite, unit, building, floo	,				MF Nu	ımber			
City	State/Provi	nce/Region			Establ	ishmen	nt DUNS Numb	per	
Country		ZIP or Pos							
Is the establishment new to the application?	Yes	No	What is the	e status of the e	establish Act		Inactive	Withdra	wn
Establishment Contact Information at the site/ Name of Contact for the Establishment Address 1 (Street address, P.O. box, company					Teleph	none Nu	umber (Include	e area code)
Address 2 (Apartment, suite, unit, building, floo	or, etc.)				FAX N	lumber	(Include area	code)	
City	State/Provi	nce/Region			Email	Addres	S		
Country		ZIP or Pos	tal Code						
Manufacturing Steps and/or Type of Testing					for i			s No	□ N/A
							Continuation P		
29. Cross References (List related BLAs, INDs, N	IDAs, PMAs	, 510(k)s, IL	DES, BMFS,	MAFs, and DN	/IFs refe	renced	in the current	С	ontin. age for #28
30. This application contains the following items ((Select all the	at apply)							
1. Index 2. Labeling (Select one	e): Dra	ft Labeling	Final F	Printed Labeling	9	3	. Summary (2	1 CFR 314.	50 (c))
B. Samples	s (21 CFR 31	4.50 (e)(1);	21 CFR 601	mation (e.g., 21 1.2 (a)) (Submit 14.50(e)(2)(i); 2	t only up	on FD	, , , ,	601.2)	
5. Nonclinical pharmacology and toxicology (e.g., 21 CFR 314.50(d)(2); 21 CFR 60		_		man pharmaco g., 21 CFR 314			•	ction	
7. Clinical microbiology section (e.g., 21 C	CFR 314.50(d	d)(4))	8. Clir	nical data section	on (e.g.,	21 CF	. , , ,); 21 CFR 6	

Previous Page Next Page	9					
31. This application contains the following it	ems (Continued; selec	ct all that apply)				
9. Safety update report (e.g., 21 CF 21 CFR 601.2)	R 314.50(d)(5)(vi)(b);	10. Statis	stical section	on (e.g., 21 CFR 3	314.50(d)(6); 21 C	FR 601.2)
11. Case report tabulations (e.g., 20)	1 CFR 314.50(f)(1);	12. Case	report for	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)				ation with respect 1 U.S.C. 355 (b)(2	to any patent tha 2) or (j)(2)(A))	t claims the
15. Establishment description (21 C)	FR Part 600, if applica	able) 16. Deba	rment cert	ification (FD&C A	ct 306 (k)(1))	
17. Field copy certification (21 CFR	314.50 (I)(3))			,	Form FDA 3397, Gi 2, or MDUFA Form	
19. Financial Disclosure Information	n (21 CFR Part 54)	·				
20. Other (Specify):						
CERTIFICATION I agree to update this application with new swarnings, precautions, or adverse reactions requested by FDA. If this application is apprincluding, 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 If this application applies to a drug product the product until the Drug Enforcement Adm The data and information in this submission Warning: A willfully false statement is a crin	in the draft labeling. I coved, I agree to compulations in 21 CFR Part 600 tarts 201, 606, 610, 66 or biological product, in application in FD&C R 314.80, 314.81, 600 mental impact laws. hat FDA has proposed inistration makes a fir have been reviewed a	agree to submit safety oly with all applicable la arts 210, 211 or applicable. 50, and/or 809. prescription drug adve C Act section 506A, 21 of 0.80, and 600.81. d for scheduling under thal scheduling decision and, to the best of my leady	r update re ws and req ble regulat rtising reg CFR 314.7 the Contro	ports as provided gulations that app ions, Parts 606, a ulations in 21 CF '1, 314.72, 314.9	d for by regulation by to approved appr	or as opplications, on an arket
32. Typed Name and Title of Applicant's Re	sponsible Official				33. Date (mm/d	Id/yyyy)
34. Telephone Number (Include country code if applicable and area code)	35. FAX Number (Incapplicable and an		36. Emai	I Address		
37. Address of Applicant's Responsible Offi	cial					
Address 1 (Street address, P.O. box, com	npany name c/o)					
Address 2 (Apartment, suite, unit, building	a. floor. etc.)			_		
()						
City	State/Province	/Region				
Country	ZIF	P or Postal Code		-		
38. Signature of Applicant's Responsible Of Other Authorized Official	ficial or Sign	n 39. Countersi	gnature of	Authorized U.S. A	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 coll this burden estimate or any other aspect of for reducing this burden to the address to the "An agency may not conduct or sponsor, and	on is estimated to average the existing data sources election of information. So this information collections in the end of the end	s, gather and maintain the send comments regarding on, including suggestions	, De F	epartment of Heal ood and Drug Adm office of Operations aperwork Reduction RAStaff@fda.hhs.	Ith and Human Ser ninistration Son Act (PRA) Staff	
collection of information unless it displays a d					FF EMAIL ADDRE	

Proposed Indication for Use Is this indication for a rare disease (prevalence <200,000 in U.S.)? Yes N	Remove Continuation Page Return to F	orm
15A. Proposed Indication for Use 1s this indication for a rare disease (prevalence <200,000 in U.S.)? Yes No No No No No No No N		
Does this product have an FDA Orphan Designation number for this indication? Yes No		completing all elements within each set that you start.
Orphan Designation for this indication: Sesting Ses	5A. Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)?
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Does this product have an FDA Orphan Designation for this indication? Yes No No No No No No No N	5A. Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)? Yes
Orphan Designation for this indication? Yes No No No No No No No N		
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Does this product have an FDA Orphan Designation for this indication? Yes No	5A. Dangered Indication for Lie	
Orphan Designation for this indication? Yes No Designation number for this indication:	oa. Proposed indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)?
		Orphan Designation for this Designation number for this
15B. SNOMED CT Indication Disease Term		□ Vos □ No
		☐ Yes ☐ NO ☐

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Add Second Continuation Page for #15

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ECOND CONTINUATION PAGE FOR ITE	-
5A. Proposed Indication for Use	ded, completing all elements within each set that you start.
	Is this indication for a rare disease (prevalence <200,000 in U.S.)? Yes In 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	L Yes L No
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	i i i i i i i i i i i i i i i i i i i
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? If yes, provide the Orphan Designation number for this indication:
5B. SNOMED CT Indication Disease Term	L Yes L No
5A. Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)? Yes
	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	
	t .
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	
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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	

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 of	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

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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, floo	or, 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 the Yes □ No □ 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)	
Address 2 (Apartment, suite, unit, building, floo	or, 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 the Yes □ No □ 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) 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

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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		Establishmer	nt DUNS Num	ber
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?	s No N/A

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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	Establishes 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 to	o Form			
IFTH CONTINUATION PAGE FOR ITEM 27	' – Establis	hment Info	ormation	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	or, 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	/facility			
Name of Contact for the Establishment				Telephone Number (Include area code)
Address 1 (Street address, P.O. box, company	/ name c/o)			EAV Number (Include over code)
Address 2 (Apartment, suite, unit, building, floor	or, etc.)			FAX Number (Include area code)
City	State/Prov	ince/Region	ı	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 2 (Apartment, suite, unit, building, floor	or, etc.)			MF Number
City	State/Prov	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 Pending	establishment? Active Inactive Withdrawn
Establishment Contact Information at the site	/facility			
Name of Contact for the Establishment	<u> </u>			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.) 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

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(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

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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, 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?	Yes	No	What is the	status of the e	stablishment?	Withdrawn
Establishment Contact Information at the site/i				, · · · J		
Name of Contact for the Establishment	raciiity				Telephone Number (Include a	rea code)
Address 1 (Street address, P.O. box, company	name c/o)				FAX Number (Include area co	(do)
Address 2 (Apartment, suite, unit, building, floor	r, etc.)				FAX Number (include area co	ide)
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 for inspection? If No, when will site be ready? (mm/dd/yyyy)	□ 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	tal Code		Establishment DUNS Number	•
Is the establishment new to the application?	Yes	No	What is the	status of the e	stablishment?	
_					Active Inactive	Withdrawn
Establishment Contact Information at the site/	facility		'		Active Inactive	Withdrawn
Establishment Contact Information at the site/	facility					
Name of Contact for the Establishment	•				Active Inactive Inactive Include a	
Name of Contact for the Establishment Address 1 (Street address, P.O. box, company	name c/o)					rea code)
Name of Contact for the Establishment Address 1 (Street address, P.O. box, company Address 2 (Apartment, suite, unit, building, floor	name c/o) r, etc.)				Telephone Number (Include a	rea code)
Name of Contact for the Establishment Address 1 (Street address, P.O. box, company Address 2 (Apartment, suite, unit, building, floor City	name c/o) r, etc.)	ince/Region			Telephone Number (Include a	rea code)
Name of Contact for the Establishment Address 1 (Street address, P.O. box, company Address 2 (Apartment, suite, unit, building, floor	name c/o) r, etc.)				Telephone Number (Include a FAX Number (Include area co	rea code)

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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

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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			
ty 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	
		INU		relialing	Active	Inactive	VIIIIIIIIAWII	
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)					FAX Number (Include area code)			
Address 2 (Apartment, suite, unit, building, floo	r, etc.)				I AX Number	(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, floo					Registration MF Number	(FEI) Number		
	or, etc.)	vince/Region	1			(FEI) Number		
Address 2 (Apartment, suite, unit, building, floo	or, etc.)	vince/Region			MF Number	(FEI) Number		
Address 2 (Apartment, suite, unit, building, floo City Country	or, etc.)		stal Code	status of the	MF Number Establishme	nt DUNS Num		
Address 2 (Apartment, suite, unit, building, floo	or, etc.)		stal Code	e status of the	MF Number	nt DUNS Num		
Address 2 (Apartment, suite, unit, building, floo City Country	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?	State/Pro	ZIP or Pos	stal Code	_	MF Number Establishmenta	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/	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	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, floor 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)	State/Pro Yes fracility name c/o) or, 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, 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	State/Pro Yes fracility name c/o) or, 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)	

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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)

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Continue your answer in the space below.					
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