	Next Page	Exp	ort Data	Import Data	F	Reset Form			
DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Form Approved: OMB No. 0910-0338 Expiration Date: March 31, 2020 See PRA Statement on page 3. 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: March 31, 2020 See PRA Statement on page 3.									
	APPLICANT INFORMATION 2. Name of Applicant								
3. Telephone Number (Inclu	3. Telephone Number (Include country code if applicable and area code) 4. Facsimile (FAX) Number (Include country code if applicable and area code)								
5. Applicant Address	5. Applicant Address								
	Address 1 (Street address, P.O. box, company name c/o) Email Address								
Address 2 (Apartment, su	uite, unit, building, floc	or, etc.)			A	oplicant DUNS			
City		State/Pro	vince/Region						
					U	.S. License Nur	ber if previously issued		
Country			ZIP or Post	al Code					
6. Authorized U.S. Agent (R	equired for non-U S	applicants)							
Authorized U.S. Agent Na	•	<u>«թթ</u>			Te	elephone Numbe	er (Include area code)		
							. ,		
Address 1 (Street addres	s, P.O. box, company	name c/o)			F/	AX Number (Incl	lude area code)		
Address 2 (Apartment, su	uite, unit, building, floc	or, etc.)				mail Address			
City		State				Indii Auuress			
		Cluto				.S. Agent DUNS			
ZIP Code									
PRODUCT DESCRIPTIO	N 7. NE	DA, ANDA,	or BLA Applic	ation Number	8. Sup	plement Numbe	r (If applicable)		
9. Established Name (e.g., µ	proper name, USP/U	SAN name))						
10. Proprietary Name (Trade	e Name) (If any)								
11. Chemical/Biochemical/B	Blood Product Name	(If any)							
		in any)							
12. Dosage Form		13. Streng	ths		14.	14. Route of Administration			
15A. Proposed Indication for	r Use		Is this indication	on for a rare disease (prevaler	 וכפ <200,000 in	U.S.)? 🗌 Yes 🗌 No		
			Does this proc Orphan Desig indication?	luct have an FDA nation for this	Desi	s, provide the Or gnation number ation:			
				🗌 Yes 🗌 No					
15B. SNOMED CT Indication	n Disease Term <i>(Use</i>	continuatio	on page for ea	ch additional indicati	on and r	espective codec	d disease term)		
APPLICATION INFORMA	TION 16 A	pplication	Type 🗆 .						
		Select one		New Drug Application	. ,	•	cs License Application (BLA)		
17. If an NDA, identify the ty	/pe 505(b)(1)	505	(b)(2)	18. If a BLA, identify			l(a) 351(k)		
19. If a 351(k), identify the h				r the submission					
 19. If a 351(k), identify the biological reference product that is the basis for the submission. Name of Biologic: Holder of Licensed Application: 									
20. If an ANDA, or 505(b)(2)), identify the listed d	ug product	that is/are the						
Name of Davage	,, ,		·	Application Number		Upon Product:			
Indicate Patent Certification:	P1	P2	P3 P	4 Section viii	- MOU	Statemer	nt of no relevant patents		

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21	21. Submission (See instructions) Original Labeling Supplement CMC Supplement Efficacy Supplement Annual Report Product Correspondence REMS Supplement Postmarketing Requirements or Commitments Periodic Safety Report Request for Proprietary Name Review Other (Specify):							
22	2. Submission Presubmission Amendment 23. If a supplement, identify the appropriate category. CBE Prior Approval (PA) Initial Submission Resubmission CBE-30							
	4. For Originals and all Supplements, is the product a combination product (21 CFR 3.2(e))? Combination Product Type (See instructions) Request for Designation (RFD) Number							
	Only Pediatric data? Yes No		nformation? Io	26. Proposed Marketing Prescription Proc				nter Product (OTC)
27	. Reasons for Submission							
28	. Establishment Information (Full establishment	t information	should be p	provided in the body of the	applica	tion.)		
	Establishment Name							
	Address 1 (Street address, P.O. box, company	,			Regist	ration	(FEI) Number	
	Address 2 (Apartment, suite, unit, building, floor, etc.)					Imber		
	City	State/Provi	nce/Region					
	Country ZIP or Postal Code				Establishment DUNS Number			
	Is the establishment new to the application? What is the status of the Ves No Pending						Inactive	Withdrawn
	Establishment Contact Information at the site/	facility						
	Name of Contact for the Establishment				Teleph	ione Ni	umber <i>(Include</i>	area code)
	Address 1 (Street address, P.O. box, company	name c/o)			ΕΔΥ Ν	umber	(Include area	codel
	Address 2 (Apartment, suite, unit, building, floo	r, etc.)						
	City	State/Provi	nce/Region		Email Address			
	Country		ZIP or Pos	tal Code				
Manufacturing Steps and/or Type of Testing Is the site read for inspection? If No, when wil ready? (mm/dd						ion?	No N/A	
						C	Continuation P	age for #28
29	. Cross References (List related BLAs, INDs, N	IDAs, PMAs	, 510(k)s, ID	DEs, BMFs, MAFs, and DM	IFs refe	renced	I in the current	application.)
								Contin. Page for #29
30	. This application contains the following items (Select all the	at apply)					
	1. Index 2. Labeling (Select one	e): 🗌 Drat	ft Labeling	Final Printed Labeling	9	3	3. Summary (2	1 CFR 314.50 (c))
	B. Samples	s (21 CFR 31	4.50 (e)(1);	ontrols information (e.g., 21 21 CFR 601.2 (a)) (Submit ., 21 CFR 314.50(e)(2)(i); 2	t only up	on FD		601.2)
	5. Nonclinical pharmacology and toxicolog (e.g., 21 CFR 314.50(d)(2); 21 CFR 60	gy section		6. Human pharmaco (e.g., 21 CFR 314	kinetics	and bio		ction
	7. Clinical microbiology section (e.g., 21 C		1)(4))	8. Clinical data section				; 21 CFR 601.2)
							Item 30 co	ontinued on page 3

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30. This application contains the following items (Continued; select all that apply)									
9. Safety update report (e.g., 21 CFR 3 21 CFR 601.2)	14.50(d)(5)(vi)(b);	10. Statis	stical sectio	n (e.g., 21 CFR 3	314.50(d)(6); 21 CFR 601.2)				
11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 60 21 CFR 601.2)									
13. Patent information on any patent that claims the drug/ biologic (21 U.S.C. 355(b) or (c)) 14. A patent certification with respect to any patent that claims the drug/biologic (21 U.S.C. 355 (b)(2) or (j)(2)(A))									
15. Establishment description (21 CFR	Part 600, if applicable)	🗌 16. Deba	rment certi	fication (FD&C A	ct 306 (k)(1))				
17. Field copy certification (21 CFR 31	4.50 (l)(3))				Form FDA 3397, GDUFA Form 2, or MDUFA Form FDA 3601)				
19. Financial Disclosure Information (2	1 CFR Part 54)								
20. Other (Specify):									
 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: Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820. Biological establishment standards in 21 CFR Part 600. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81. Local, state, and Federal environmental impact laws. If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision. The data and information in this submission have been reviewed 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. 31. Typed Name and Title of Applicant's Responsible Official									
33. Telephone Number (Include country code if applicable and area code) 34	. FAX Number (Include ca applicable and area cod		35. Email	Address					
36. Address of Applicant's Responsible Official			1						
Address 1 (Street address, P.O. box, compa	ny name c/o)								
Address 2 (Apartment, suite, unit, building, f	oor, etc.)			-					
City	State/Province/Region	n		-					
Country ZIP or Postal Code									
37. Signature of Applicant's Responsible Offici Other Authorized Official	al or Sign	38. Countersi	gnature of	Authorized U.S. <i>i</i>	Agent Sign				
The information below applies only to requirements of the Paperwork Reduction Act of 1995. The burden time for this collection of information is estimated to average 24 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding									

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this burden estimate or any other aspect of this information collection, including suggestions

Office of Operations Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

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FIRST CONTINUATION PAGE FOR ITEM 15 – Propo	osed Indication for Use	
Please fill out as many sets of answers as needed, comple	eting 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.)? 🗌 Yes 🗌 No
	Does this product have an FDA Orphan Designation for this indication?	the Orphan umber for this
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 Designation nu indication:YesNo	the Orphan umber for this
15B. SNOMED CT Indication Disease Term	l i	
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?	the Orphan umber for this
15B. SNOMED CT Indication Disease Term		
15A. Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,	,000 in U.S.)? 🗌 Yes 🗌 No
	Does this product have an FDA Orphan Designation for this indication?	
15B. SNOMED CT Indication Disease Term		
15A. Proposed Indication for Use		
TOA. 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?If yes, provide Designation nu indication:YesNo	
15B. SNOMED CT Indication Disease Term	۱	
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 Designation nu indication:YesNo	
15B. SNOMED CT Indication Disease Term	۱	
Remove Continuation Page Return to Form	Add Sec	cond Continuation Page for #15

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ECOND CONTINUATION PAGE FOR IT	-
	eded, 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?If yes, provide the Orphan Designation number for this indication:YesNo
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 If yes, provide the Orphan Orphan Designation for this Designation number for this indication? 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 If yes, provide the Orphan Orphan Designation for this Designation number for this indication? indication:
15B. SNOMED CT Indication Disease Term	
I5A. Proposed Indication for Use	
	Is this indication for a rare disease (prevalence <200,000 in U.S.)? Yes N Does this product have an FDA Orphan Designation for this indication? If yes, provide the Orphan Designation number 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 FDAIf yes, provide the OrphanOrphan Designation for thisDesignation number for thisindication?indication:
	Yes No
5B. SNOMED CT Indication Disease Term	
I5A. 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	
Remove Continuation Page Retu	rn to Form

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FIRST CONTINUATION PAGE FOR ITEM 28 – Establishment Information					Provide information for additional establishments below, as needed.
Establishment Name					
Address 1 (Street address, a	P.O. box, company r		Registration (FEI) Number		
Address 2 (Apartment, suite, unit, building, floor, etc.)					MF Number
City		State/Provi	nce/Region	l	
Country			ZIP or Pos	stal Code	Establishment DUNS Number
Is the establishment new to	the application?	establishment?			
Establishment Contact Info	rmation at the site/fa	acility			
Name of Contact for the Est	ablishment				Telephone Number (Include area code)
Address 1 (Street address,	P.O. box, company r	name c/o)			EAV Number (Include area ande)
Address 2 (Apartment, suite	e, unit, building, floor,	, etc.)			FAX Number (Include area code)
City		State/Provi	nce/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 r	name c/o)			Registration (FEI) Number
Address 2 (Apartment, suite	e, unit, building, floor	, etc.)			MF Number
City		State/Provi	nce/Region		
Country			ZIP or Pos	stal Code	Establishment DUNS Number
Is the establishment new to	the application?			What is the status of the	
		Yes	No	Pending	Active Inactive Withdrawn
Establishment Contact Info		acility			
Name of Contact for the Est					Telephone Number (Include area code)
Address 1 (Street address,	P.O. box, company r	name c/o)			FAX Number (Include area code)
Address 2 (Apartment, suite	e, unit, building, floor,	etc.)			
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)
					Add Second Continuation Page for #28
ORM FDA 356h (04/18)			Daga	X of X	

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ECOND CONTINUATION PAGE FOR ITEM 28 – Establishment Information					Provide information for additional establishments below, as needed.		
Establishment Name							
Address 1 (Street address, P.O. box, company name c/o)				F	Registration (FEI) Number		
Address 2 (Apartment, suite, unit, building, floo	or, etc.)			N	/F Number		
City	State/Prov	ince/Region					
Country		ZIP or Pos	tal Code	E	Establishment DUNS Number		
Is the establishment new to the application?	Yes	No	What is the status of Pendi		ablishment?] Active 🗌 Inactive 🗌 Withdrawn		
Establishment Contact Information at the site	/facility						
Name of Contact for the Establishment				T	elephone Number (Include area code)		
Address 1 (Street address, P.O. box, company	/ name c/o)						
Address 2 (Apartment, suite, unit, building, floo	or, etc.)				AX Number (<i>Include area code</i>)		
City	State/Province/Region				Email Address		
Country		ZIP or Pos	tal Code				
Manufacturing Steps and/or Type of Testing		1			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)			F	Registration (FEI) Number		
Address 2 (Apartment, suite, unit, building, floo	or, etc.)			N	//F Number		
City	State/Prov	ince/Region					
Country		ZIP or Pos	tal Code	E	Establishment DUNS Number		
Is the establishment new to the application?	Yes	No	What is the status of Pendi		ablishment?] Active 🔲 Inactive 🗌 Withdrawn		
Establishment Contact Information at the site	/facility		1	-			
Name of Contact for the Establishment				Т	elephone Number (Include area code)		
Address 1 (Street address, P.O. box, company	/ name c/o)						
Address 2 (Apartment, suite, unit, building, floo	or, etc.)			F	AX Number (Include area code)		
City	State/Province/Region						
Country		ZIP or Pos	tal 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)		
					Add Third Continuation Page for #28		
RM FDA 356h (04/18)		Page	X of X	Remov	ve Continuation Page Return to Form		

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IRD CONTINUATION PAGE FOR ITEM 28 – Establishment Information					Provide information for additional establishments below, as needed.			
Establishment Name				I				
Address 1 (Street address, P.O. box, company name c/o)						(FEI) Numbe	er	
Address 2 (Apartment, suite, unit, building, floor, etc.)					MF Number			
City	State/Prov	ince/Region						
Country		ZIP or Pos	tal Code		Establishmer	nt DUNS Nur	nber	
Is the establishment new to the application?	What is the status of the Yes No Pending				e establishment?			
Establishment Contact Information at the site/	facility							
Name of Contact for the Establishment					Telephone N	umber <i>(Inclu</i>	de 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 are	a code)	
City	State/Province/Region					38		
Country	ZIP or Postal Code							
Manufacturing Steps and/or Type of Testing				1	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) Numbe	r	
Address 2 (Apartment, suite, unit, building, floo	or, 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 o		stablishment?	Inactive	Withdrawn	
Establishment Contact Information at the site/	facilitv							
Name of Contact for the Establishment					Telephone N	umber (Inclu	de 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 are	ea code)	
City	State/Province/Region				Email Addres	s		
Country		ZIP or Pos	tal Code					
Manufacturing Steps and/or Type of Testing		1			Is the site r for inspecti If No, wher ready? (mr	ion?	ies 🗌 No 🗌 N/A	
					Add Fo	ourth Continu	ation Page for #28	
RM FDA 356h (04/18)		Page	X of X	Remo	ove Continuati	ion Page	Return to Form	

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URTH CONTINUATION PAGE FOR ITEM	28 – Estab	lishment l	nformation		Provide information for additional establishments below, as needed.		
Establishment Name				·			
Address 1 (Street address, P.O. box, company		Registration (FEI) Number					
Address 2 (Apartment, suite, unit, building, floor	r, etc.)				MF Number		
City	State/Provi	ince/Region					
Country		ZIP or Pos	tal Code		Establishment DUNS Number		
					te blie bere en to		
Is the establishment new to the application?	Yes	No	What is the status of		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 i	name c/o)						
Address 2 (Apartment, suite, unit, building, floor	r etc.)				FAX Number (Include area code)		
City	State/Provi	ince/Region			Email Address		
Country		ZIP or Pos	tal Code				
Manufacturing Steps and/or Type of Testing					Is the site ready Yes No N/ for inspection? If No, when will site be ready? (mm/dd/yyyy)		
Establishment Name							
Address 1 (Street address, P.O. box, company i	name c/o)				Registration (FEI) Number		
Address 2 (Apartment, suite, unit, building, floor	r, etc.)				MF Number		
City	State/Provi	ince/Region					
Country		ZIP or Pos	tal Code		Establishment DUNS Number		
Is the establishment new to the application?		No	What is the status of		stablishment?		
Establishment Contact Information at the site/f	_ Yes			iy L			
Name of Contact for the Establishment					Telephone Number (Include area code)		
Address 1 (Street address, P.O. box, company a	name c/o)						
Address 2 (Apartment, suite, unit, building, floor		FAX Number (Include area code)					
City							
Country		ZIP or Pos		Email Address			
Manufacturing Steps and/or Type of Testing		1			Is the site ready Yes No N/ for inspection? If No, when will site be ready? (<i>mm/dd/yyyy</i>) Add Fifth Continuation Page for #28		
RM FDA 356h (04/18)		Page	X of X	Remo	ve Continuation Page Return to Form		

FIFTH CONTINUATION PAGE FOR ITEM 28	Provide information for additional					
Establishment Name	establishments below, as needed.					
Address 1 (Street address, P.O. box, company			Registration (FEI) Number			
Address 2 (Apartment, suite, unit, building, floor	1		MF Number			
City	State/Province/Region		Establishment DUNS Number			
Country	ZIP or Pos	tal Code				
Is the establishment new to the application?	Yes No	What is the status of the Pending	establishment?			
Establishment Contact Information at the site/f	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, floor	r, etc.)		FAX Number (Include area code)			
City	State/Province/Region		Email Address			
Country	ZIP or Pos	tal Code				
Manufacturing Steps and/or Type of Testing	Manufacturing Steps and/or Type of Testing					
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 Pos	tal Code	Establishment DUNS Number			
Is the establishment new to the application?	Yes No	What is the status of the Pending	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	Address 1 (Street address, P.O. box, company name c/o)					
Address 2 (Apartment, suite, unit, building, floor	FAX Number (Include area code)					
City	Email Address					
Country	Country ZIP or Postal Code					
Manufacturing Steps and/or Type of Testing			Is the site ready for inspection? Yes No N/A If No, when will site be ready? (mm/dd/yyyy) Add Sixth Continuation Page for #28			

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IXTH CONTINUATION PAGE FOR ITEM 28 – Establishment Information					Provide information for additional establishments below, as needed.		
Establishment Name				I			
Address 1 (Street address, P.O. box, company name c/o)						(FEI) Numbe	er
Address 2 (Apartment, suite, unit, building, floo	or, etc.)				MF Number		
City	State/Prov	ince/Region					
Country		ZIP or Pos	tal Code		Establishmen	nt DUNS Nu	mber
Is the establishment new to the application?	Yes	No	What is the status o		tablishment?	Inactive	Withdrawn
Establishment Contact Information at the site.							
Name of Contact for the Establishment	Tacinty			· ·	Telephone Nu	umber <i>(Inclu</i>	ide 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 are	ea code)
City	State/Prov	ince/Region			Email Addres	s	
Country		ZIP or Pos	tal Code				
Manufacturing Steps and/or Type of Testing		,			Is the site r for inspection If No, when ready? (mr	on?'	/es 🗌 No 🗌 N/A
Establishment Name Address 1 (Street address, P.O. box, company	/ name c/o)				Registration ((FEI) Numbe	er
Address 2 (Apartment, suite, unit, building, floo	or, etc.)				MF Number		
City	State/Prov	ince/Region					
Country		ZIP or Pos	tal Code		Establishmen	nt DUNS Nu	mber
Is the establishment new to the application?	Yes	No	What is the status o		tablishment?	Inactive	Withdrawn
Establishment Contact Information at the site.	/facility						
Name of Contact for the Establishment					Telephone Nu	umber (Inclu	ide area code)
Address 1 (Street address, P.O. box, company	/ name c/o)						
Address 2 (Apartment, suite, unit, building, floor, etc.)						(Include are	ea code)
City State/Province/Region					Email Addres	S	
Country			-				
Manufacturing Steps and/or Type of Testing					ready? (mn	on? n will site be m/dd/yyyy)	/es 🗌 No 🗌 N//
					Add Sev	venth Contin	uation Page for #28
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EVENTH CONTINUATION PAGE FOR ITEM 28 – Establishment Information				
Address 1 (Street address, P.O. box, company name c/o)				
				MF Number
Provi	ince/Region			
	ZIP or Pos	tal Code		Establishment DUNS Number
	No	What is the status o		establishment?
			ing	
				Telephone Number (Include area code)
<i>o)</i>				
				FAX Number (Include area code)
Provi	ince/Region			Email Address
	ZIP or Pos	tal 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? (<i>mm/dd/yyyy</i>)
<i>o)</i>				Registration (FEI) Number
				MF Number
Prov	ince/Region			
	ZIP or Pos	tal Code		Establishment DUNS Number
	No	What is the status o		establishment?
				Telephone Number (Include area code)
<i>o)</i>				
Address 2 (Apartment, suite, unit, building, floor, etc.)				
Provi	ince/Region		Email Address	
ntry ZIP or Postal Code				
				Is the site ready Yes No N/A for inspection? If No, when will site be ready? (mm/dd/yyyy)
	Deec	Y of Y		Add Eighth Continuation Page for #28
		Page	Page X of X	Page X of X

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IGHTH CONTINUATION PAGE FOR ITEM 2	Provide information for additional establishments below, as needed.				
Establishment Name					
Address 1 (Street address, P.O. box, company of	Registration (FEI) Number				
Address 2 (Apartment, suite, unit, building, floor	; etc.)		MF Number		
City	State/Provi	ince/Region	-		
Country		ZIP or Postal Code	Establishment DUNS Number		
Is the establishment new to the application?	Yes	What is the status of the No Pending	establishment?		
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 i	name c/o)		-		
Address 2 (Apartment, suite, unit, building, floor	; etc.)		FAX Number (Include area code)		
City	State/Provi	ince/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? (<i>mm/dd/yyyy</i>)			
Establishment Name					
Address 1 (Street address, P.O. box, company i	name c/o)		Registration (FEI) Number		
Address 2 (Apartment, suite, unit, building, floor	; etc.)		MF Number		
City	State/Provi	ince/Region	-		
Country		ZIP or Postal Code	Establishment DUNS Number		
Is the establishment new to the application?	Yes	What is the status of the No Pending	establishment?		
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 i	name c/o)				
Address 2 (Apartment, suite, unit, building, floor	FAX Number (Include area code)				
City	State/Provi	ince/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)				
			Add Ninth Continuation Page for #28		

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NINTH CONTINUATION PAGE FOR ITEM 28	Provide information for additional establishments below, as needed.				
Establishment Name					
Address 1 (Street address, P.O. box, company	Registration (FEI) Number				
Address 2 (Apartment, suite, unit, building, floo	r, etc.)			MF Number	
City	State/Provi	ince/Region			
Country	1	ZIP or Post	al Code	Establishment DUNS Number	
Is the establishment new to the application?	Yes	No	What is the status of the Pending	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)				
Address 2 (Apartment, suite, unit, building, floo	r, etc.)			FAX Number (Include area code)	
City	State/Provi	ince/Region		Email Address	
Country		ZIP or Post	al Code		
Manufacturing Steps and/or Type of Testing	Manufacturing Steps and/or Type of Testing				
Establishment Name Address 1 (Street address, P.O. box, company				Registration (FEI) Number	
Address 2 (Apartment, suite, unit, building, floo	r, etc.)			MF Number	
City	State/Provi	ince/Region			
Country		ZIP or Post	al 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/	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, floo					
City	Email Address				
Country	al 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? (<i>mm/dd/yyyy</i>)	
				Add Tenth Continuation Page for #28	
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TENTH CONTINUATION PAGE FOR ITEM 28	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/Provi	ince/Region						
Country		ZIP or Postal C	Code	Establishment DUNS Number				
Is the establishment new to the application?	Yes	Wh No	at is the status of the o	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)							
Address 2 (Apartment, suite, unit, building, floor	r, etc.)			FAX Number (Include area code)				
City	State/Provi	ince/Region		Email Address				
Country	1	ZIP or Postal C	Code					
	Manufacturing Steps and/or Type of Testing							
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/Provi	ince/Region						
Country		ZIP or Postal C	Code	Establishment DUNS Number				
Is the establishment new to the application?	Yes	Wh No	at is the status of the o	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	Address 1 (Street address, P.O. box, company name c/o)							
Address 2 (Apartment, suite, unit, building, floor	FAX Number (Include area code)							
City State/Province/Region				Email Address				
Country	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)							

CONTINUATION PAGE FOR ITEM 29 – Cross References

Continue your answer in the space below.

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