## **Exhibit 8**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

## PATENT INFORMATION SUBMITTED WITH THE FILING OF AN NDA, AMENDMENT, OR SUPPLEMENT

For Each Patent That Claims a Drug Substance

Form Approved: OMB No. 0910-0001
Expiration Date: 03/31/2024
See OMB Statement on last page.

See OND Statement on last page.
NDA Number
Name of NDA Applicant

(Active Ingredient), Drug Composition) an		-							
Refer to instruc	tion sheet (l	FORM FI	DA 3542a SUPPLE	MEN	T) for more	information	٠.		
The following is provided in accorda	nce with Sec	ction 505	(b) and (c) of the Fe	edera	l Food, Drug	g, and Cosme	etic A	ct (FD&C Act).	
Active Ingredient(s)									
Trade Name (or proposed Trade Name)			Strength(s)	Include	e applicable Pro	duct Number, if a	availab	ole - See instructions)	)
Dosage Form(s)	Route(	s) of Adn	ministration		Type o	of Use			
					☐ Pre	escription		Over-the-Counte	ər
This patent declaration form is required supplement as required by 21 CFR 314 approval of an NDA or supplement, or w Form FDA 3542 pursuant to 21 CFR 314 will not list or publish patent information is	4.53 at the a ithin thirty (30 4.53(c)(2)(ii) v	ddress p )) days o vith all of	provided in 21 CFR of issuance of a new fither required information.	314.9 pater ation	53(d)(4). Wi nt, a new pa based on th	thin thirty (30 tent declaration e approved N	) day on mu IDA c	ys after the date ust be submitted or supplement. Fl	of on DA
FDA will not list patent information if to or the patent declaration indicates the				the	information	required by	21 C	FR § 314.53(c)(	2)
For each patent submitted for the per information described below. If you a complete the section above and sect	re not subn	nitting a							
1. GENERAL (Please note: If 1.a is N	OT entered,	then sec	ction 5 later in form	must	t be marked	as "Yes" in i	ts ch	eck box.)	
a. United States Patent Number			b. Issue Date of Patent		с. Ехр	c. Expiration Date of Patent			
d. Name of Patent Owner									
Address (of Patent Owner)			City						
State/Province/Region Count			ountry			ZIP or Pos	tal Co	ode	
FAX Number (if available)  Telephone Num				E-M	ail Address	(if available)			
Click for additional set of 1.d. en	tries (includes	s all addr	ess and related conta	ct ite	ms above). N	May be repeate	ed.	Add Section 1.d.	

Name of U.S. agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent.		Address (of agent or re	presentat	tive name	ed in 1.e.)				
(	States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the FD&C Act and 21 CFR 314.52 and 314.95.		City/State						
ί	Jsing the checkboxes provided, indic	cate whethe		ZIP Code		FAX Nu	mber (if availab	(e)	
	he person represents the patent own applicant, or both.	ner, NDA		Zii Gode		The contained of the contained of			
	Name:			Telephone Number E-M			-Mail Address (if available)		
Repre	sents (Select one): Patent Owner NDA	A Applicant	Both						
	Click for additional set of 1.e. en	tries (include	es all	address and related conta	act items a	above). Ma	ay be repeated.	Add Section 1.e.	
T. N	ame of NDA Applicant								
Add	ress (of NDA Applicant)				City				
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FAX	( Number (if available)	Telephone	Num	nber	E-Mail A	ddress (i	f available)		
	las the patent referenced above bed product?	en submitted	d pre	viously for listing for this	drug		☐ Yes	☐ No	
	f the answer to question 1.g. is "Yes					tted Form	3542a and spe	ecify whether	
	each change is related to the patent	or related to	o an i	FDA action or procedure	<b>)</b> .				
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For	the patent referenced above, product, and/or method of use that is							substance, drug	
For pro-	the patent referenced above, product, and/or method of use that is	the subjec	ct of	the pending NDA, ame	ndment,	or suppl	ement.		
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2.6	Does the patent claim only an intermediate?		Yes	☐ No
2.7	If the patent referenced in <b>2.1</b> is a product-by-process patent, is the product claimed in the patent novel?  Not Ap	plicable	☐ Yes	☐ No
3. D	RUG PRODUCT (COMPOSITION/FORMULATION)			
3.1	Does the patent claim the drug product, as defined in 21 CFR 314.3, in the pending NDA, amendment, or supplement?		☐ Yes	☐ No
3.2	Does the patent claim only an intermediate?		☐ Yes	☐ No
3.3	If the patent referenced in <b>3.1</b> is a product-by-process patent, is the product claimed in the patent novel?	pplicable	☐ Yes	☐ No
4. N	METHOD OF USE			
app each with	A applicants must submit the information in section 4 for each method of using proval is being sought and that is claimed by the patent. An NDA applicant may the pending method of use; however, each pending method of use claimed by the patent, provide the following informate.	list together e patent mus se informati	multiple pat st be separat	ent claims for ely identified
4.1	Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement?  Yes (only one pending Yes (more than one p		, -	No
4.2	Patent Claim Number(s) (as listed in the patent) (Please separate numbers with commas.)	in <b>4.2</b> clair for which	m a pending n approval is be ding NDA, am	ing sought
4.2a	a If the answer to <b>4.2</b> is "Yes," for each pending method of use, separately identify the specific section(s) and subsection(s) of the proposed labeling for the drug product that describe the method of use claimed by the patent. If there is no applicable subsection, insert "subsection N/A". If there is more than one pending method of use, please use the "Add Section 4.2" button for additional entries as needed.		n a separate l	ine. Within each
	If more than one pending method of use, click to add a new set of Section 4.2 e.	ntries. May be	e repeated.	Add Section 4.2
5. N	IO RELEVANT PATENTS			
clair metl clair	this pending NDA, amendment, or supplement, there are no relevant patents that method the drug substance (active ingredient), drug product (formulation or composition) of hod(s) of use, for which the applicant is seeking approval and with respect to which a method of patent infringement could reasonably be asserted if a person not licensed by the ler of the patent engaged in the manufacture, use, or sale of the drug product.	I	☐ Yes	

6. DECLARATION CERTIFICATION								
5.1 The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This timesensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.								
Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.								
2 Authorized Signature of NDA Applicant or Patent Owner (Attorney, Agent, Representative or other Authorized Official) (Provide Information below)  Sign								
Countersignature of Authorized U.S	Countersign	Date Signed						
licant is authorized to sign the de-	claration but r	nay not submit it directl						
☐ NDA Applicant				(Representative) or Other				
☐ Patent Owner				(Representative) or Other				
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Number (if available)	Telephone Nu	mber	E-Mail Address (	if available)				
This section applies only to requirements of the Paperwork Reduction Act of 1995.  *DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*  The burden time for this collection of information is estimated to average 15 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 this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:  Department of Health and Human Services Food and Drug Administration Office of Operations Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov  "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."								
	The undersigned declares that the amendment, or supplement pends sensitive patent information is so this submission complies with the is true and correct.  Warning: A willfully and knowing.  Authorized Signature of NDA Application or other Authorized Official) (Provided Countersignature of Authorized U.S.  TE: Only an NDA applicant may sublicant is authorized to sign the declar applicable box and provide information.  Declar applicable Dox and provide information.  Patent Owner  This section as *DO NOT SEND YOUR  The burden time for this collection review instructions, search exist the collection of information. Search exist collection, including suggestions.  "An agency may not "An agenc	The undersigned declares that this is an accuramendment, or supplement pending under set sensitive patent information is submitted purs this submission complies with the requirement is true and correct.  Warning: A willfully and knowingly false state.  Authorized Signature of NDA Applicant or Patent or other Authorized Official) (Provide Information is continuous authorized to Sign the declaration but reck applicable box and provide information below the patent Owner.  Telephone Number (if available)  This section applies only to receive instructions, search existing data sour the collection of information. Send comments collection, including suggestions for reducing the Depart Food a Office Paperw PRASt "An agency may not conduct or spots."	The undersigned declares that this is an accurate and complete submit amendment, or supplement pending under section 505 of the Federal sensitive patent information is submitted pursuant to 21 CFR 314.53. It his submission complies with the requirements of the regulation. I ve is true and correct.  Warning: A willfully and knowingly false statement is a criminal offen.  Authorized Signature of NDA Applicant or Patent Owner (Attorney, Agent, For other Authorized Official) (Provide Information below)  Countersignature of Authorized U.S. Agent  TE: Only an NDA applicant may submit this declaration directly to the Folicant is authorized to sign the declaration but may not submit it directly each applicant authorized Official handled in the patent Owner Authorized Official handled in the collection of information is estimated to average to review instructions, search existing data sources, gather and maintain the collection of information. Send comments regarding this burden est collection, including suggestions for reducing this burden, to:  Department of Health and Human Food and Drug Administration Office of Operations Paperwork Reduction Act (PRA) PRAStaff@ifa.hhs.gov  "An agency may not conduct or sponsor, and a person is not reduced to the regarding this burden."	The undersigned declares that this is an accurate and complete submission of patent in amendment, or supplement pending under section 505 of the Federal Food, Drug, and sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am this submission complies with the requirements of the regulation. I verify under penalt is true and correct.  Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. Authorized Signature of NDA Applicant or Patent Owner (Attorney, Agent, Representative or other Authorized Official) (Provide Information below)  Countersignature of Authorized U.S. Agent  Authorized Official of FDA. 21 CFR applicable box and provide information below.  Department Official of				