Department of Health	and Human Services
Food and Drug	Administration

PATENT INFORMATION SUBMITTED UPON AND AFTER APPROVAL OF AN NDA OR SUPPLEMENT

For Each Patent That Claims a Drug Substance (Active Ingredient), Drug Product (Formulation or Composition) and/or Method of Use

 Form Approved: OMB No. 0910-0513 Expiration Date: 10/31/2016 See OMB Statement on Page 3. NDA NUMBER

22387

NAME OF APPLICANT/NDA HOLDER United Therapeutics Corp

The following is provided in accordance with	Section 505(b) and (c) of	the Federal I	Food, Dr	rug, and Cosmetic Act.	
TRADE NAME					
TYVASO					
ACTIVE INGREDIENT(S)	STRENGTH(S)				
treprostinil	0.6 mg/mL				
DOSAGE FORM Inhalation solution	APPROVAL DA July 30, 200		R SUPPLI	EMENT	
	July 30, 200	3			
This patent declaration form is required to be submitted	d to the Food and Drug Adn	ninistration (F	DA) with	in thirty (30) days after	
approval of an NDA or supplement or within thirty (30)					
address provided in 21 CFR 314.53(d)(4). To expedite			ou may s	ubmit an additional copy of	f
this declaration form to the Center for Drug Evaluation	and Research "Orange Boo	ok" staff.			
For hand-written or typewriter versions of this report not require a "Yes" or "No" response), please attach ar					es
FDA will not list patent information if you file an ind is not eligible for listing.	complete patent declaration	on or the pat	ent decl	aration indicates the pate	ent
For each patent submitted for the approved NDA of described below. If you are not submitting any pate and 6.					5
1. GENERAL					
a. United States Patent Number	b. Issue Date of Patent			tion Date of Patent	
9,358,240	June 7, 2016		May 5	, 2028	_
d. Name of Patent Owner United Therapeutics Corporation	Address (of Patent Owner) 55 T.W. Alexander Dr	rivo			
Onlied Therapedics Corporation	55 T.W. Alexander Di	ive			
	City/State				
	ZIP Code	search Triangle Park, North Carolina		(if available)	
	27709		FAX Number (if available) (919) 313-1298		
	Telephone Number		E-Mail Address (if available)		_
	(919) 485-8350	1.550		Dunither.com	
 Name of agent or representative who resides or main- tains a place of business within the United States author- ized to receive notice of patent certification under section 	Address (of agent or repres	entative named	l in 1.e.)		
505(b)(3) and (j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.52 and 314.95 (if patent owner or NDA applicant/holder does not reside or have a	City/State				
place of business within the United States)	ZIP Code	FA	X Numbe	r (if available)	
	The last sector is		4-11-6-1-6		
	Telephone Number	E-N	viail Addre	ess (if available)	
f. Is the patent referenced above a patent that has been submitted previously for the approved NDA or supplement referenced above?			Yes	No No	
g. If the patent referenced above has been submitted previou date a new expiration date?	sly for listing, is the expiration		Yes	□ No	
FORM FDA 3542 (11/13)				Pa	ge 1
				r a	

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product, or method of use t you file an incomplete pate consider an incomplete pat	that is the subject of nt declaration or the ent declaration to	following information on each patent that claims of the approved NDA or supplement. FDA will not ne patent declaration indicates the patent is not e be a declaration that does not include a response le to the patent referenced above.	list patent in ligible for list	formation if ing. FDA will
2. Drug Substance (Active I	ngredient)			
2.1 Does the patent claim the dr described in the approved N	•	e active ingredient in the drug product	Yes	No No
2.2 Does the patent claim a drug ingredient described in the N		ifferent polymorph of the active	Yes	🗙 No
demonstrating that a drug pr	oduct containing the p	y that, as of the date of this declaration, you have test data olymorph will perform the same as the drug product ed is described at 21 CFR 314.53(b).	Yes	□ No
2.4 Specify the polymorphic form	n(s) claimed by the pat	tent for which you have the test results described in 2.3.		
		roved active ingredient? (Complete the information in ethod of using the approved drug product to administer	Yes	🔀 No
2.6 Does the patent claim only a	n intermediate?		Yes	🗙 No
		ess patent, is the product claimed in the tent is a product-by-process patent.)	Yes	□ No
 the answer to 2.3 is "Yes the answer to 2.5 or 2.6 the answer to 2.7 is "No. 	is "Yes."	sponse to 2.4, or,		
3. Drug Product (Compositi	on/Formulation)			
3.1 Does the patent claim the ap	pproved drug product a	is defined in 21 CFR 314.3?	Yes	🕅 No
3.2 Does the patent claim only a	n intermediate?		Yes	🔀 No
		ess patent, is the product claimed in the tent is a product-by-process patent.)	Yes	🗌 No
FDA will not list the patent in the the answer to question 3 the answer to question 3 the answer to question 3 the answer to question 3	3.1 is "No," or, 3.2 is "Yes," or,	laiming the drug product if:		
4. Method of Use				
		for each approved method of using the approved drug atent, provide the following information:	product claime	d by the patent.
4.1 Does the patent claim one of	r more approved meth	ods of using the approved drug product?	X Yes	□ No
4.2 Patent Claim Number(s) (as 1-9	listed in the patent)	Does (Do) the patent claim(s) referenced in 4.2 claim an approved method of use of the approved drug product?	🔀 Yes	□ No
4.2a If the answer to 4.2 is "Yes," identify the use with specific reference to the approved labeling for the drug product.	Tyvaso is a pros arterial hyperter for oral inhalatio	ion or method of use information as identified specifically in stacyclin vasodilator indicated for the treatment nsion (PAH) (WHO Group 1) to improve exercise on using the Tyvaso Inhalation System, which co device and its accessories.	of pulmonary e ability. Tyva	aso is intended
FORM FDA 3542 (11/13)				Page 2

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4.2. If the answer to 4.2 is "Vest also proved indication or the approved indication or mathed due the they programs PAA induces in the "Vest approved indication or mathed due the they approved they approved indication or mathed due they approved indication or approved indication or mathed due they approved indication or approved indication or mathed due they approved indication or approved indicati						
 • the answer to question 4.1 or 4.2 is "No," or • it the answer to 4.2 is "Yes" and the information requested in 4.2a and 4.2b is not provided in full. 5. No Relevant Patents For this NDA exploremt, there are no relevant patents that claim the approved drug substance (active ingredient) or the approved drug product (formulation or composition) or approved method(s) of use with ingredient) or the approved drug product (formulation or composition) or approved from the patent engaged in the manufacture, use, or sale of the drug product. 6. Declaration Certification 6. The undersigned declares that this is an accurate and complete submission of patent information for the NDA or submission groups of the Federal Food, Drug, and Cosmetic Act. This time-semsitive patent information is submitted parameters that 1 an familiar with 21 CFR 314.5.3 and this submission complex 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. 6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner (Altoney, Agent, Representative or other Authorized Official (Provide Information below) Current Quart of Qua	"Yes," also provide the information on the indication or method of use for the Orange Book	e the "Use Code" in the Orange Book, using no more than 240 total characters including spaces.) Method of treating pulmonary hypertension by administering treprostinil or a salt thereof by inhalation using a device				
• If the answer to 4.2 is "Yes" and the information requested in 4.2a and 4.2b is not provided in full. 5. No Relevant Patents For this NDA or supplement, there are no relevant patents that claim the approved drug substance (active ingredent) or the approved drug relaxion or composition or exproved method(s) of use with respect to which a claim of patent infrigment could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. 6. Declaration Certification 8.1 The undersigned declares that this is an accurate and complete submission of patent information for the NDA or supplement approved drug product. 8.2 Maning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001. 8.2 Authorized Signature of NDA Applicant/Holder or Patent Owner (Altoney, Agent, Representative or other Authorized Official (Provide information below) Patent Owner's Attorney. Agent (Representative) or Other Authorized Official Name Rex Mauthe, Vice President, Regulatory Affairs, United Therapeutics Corp Address 55 T.W. Alexander Drive ClaySitie Patent Owner's Attorney. Agent (Representative) or Other Authorized Official Name Rex Mauthe, Vice President, Regulatory Affairs, United Therapeutics Corp Address (F available) (19) 313-1298 This section applies only to requirements of the Patent Owner's Attorney. Agent (Representative) or Other Authorized (Provide an	FDA will not list the patent in t	he Orange Book as claiming	g the method of	use if:		
5. No Relevant Patents For this NDA or supplement, there are no relevant patents that claim the approved drug substance (active respect to which a claim of patent infragment could reasonably be asserted if a person not licensed by the were of the patent engaged in the manufacture, use, or sale of the drug product. 5. Declaration Certification 6.1 The undersigned declares that this is an accurate and complete submission of patent information for the NDA or supplement approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. Latest that I am familiar with 21 CFR 314.53 and this submission complex with the requirements of the regulation. I verify under penalty of pariny that the foregoing is true and correct. Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001. 6.2. Authorized Official (Provide information below) Marting: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001. 6.2. Authorized Official (Provide information below) Marting: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001. 6.2. Authorized Official (Provide information below) Marting: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001. 6.2. Authorized Official (Provide information below) Marting: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001. 6.2. Authorized Official (Provide information below) Marting: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001. 6.2. Authorized Official (Provide information below) Marting: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001. 6.2. Authorized Official (Provide information below) Marting: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001. 6.2. Authorized Official (Provide information below) Marting: A willfully and knowingly false statement i	• the answer to question	4.1 or 4.2 is "No," or	-			
For this NDA or supplement, there are no relevant patents that daim the approved drug substance (active ingredenit) or the approved drug product (formulation or composition) or approved method(s) of use with memory of the patent engaged in the manufacture, use, or sale of the drug product. 6. Declaration Certification 6.1 The undersigned declares that this is an accurate and complete submission of patent information for the NDA or supplement approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53.1 attributes submission complex 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. 6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner (Attorney, Agent, Representative or other Authorized Official (Provide information below) mauthe@unither.com Marting: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001. 6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner (Attorney, Agent, Representative or other Authorized Official (Provide information below) mauthe@unither.com Marting: A will fully and knowingly false statement is a criminal offense under 18 U.S.C. 1001. 6.2 Authorized Torical (Provide information below) Marting: A will be required to sign the declaration during to the rDA. A patent owner who is not the NDA applicant/ holder is authorized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53 (c) and (d)(4). Check applicant/Holder X NDA Applicant/Holder Authorized Official Address 5 T.W. Alexander Drive X NDA Applicant/Holder Authorized Official Address 5 T.W. Alexander Drive Address 5 T.W. Alexander D	• if the answer to 4.2 is "Y	es" and the information req	quested in 4.2a	and 4.2b is not provided in fu	Ш.	
ingrediently or the approved drug product (Granulation or composition) or approved method(s) of use with the approved drug product (Granulation economo the consonably the sector of the pattent engaged in the manufacture, use, or sale of the drug product. 6. Declaration Certification 6. The undersigned declarases that this is an accurate and complete submission of patent information for the NDA or supplement approved under section 505 of the Federal Food. Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53.1 at this submission completes 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. 6. Jober and the engage of	5. No Relevant Patents					
The undersigned declares that this is an accurate and complete submission of patent information for the NDA or supplement approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53 at 145 that 1 at maintiliar with 12 CFR 314.53 and this submission complex 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. E. Authorized Signature of NDA Applicant/Holder or Patent Owner (Atomey, Agent, Representative or other Authorized Official (Provide Information below) mauthe@unither.com During sequences and provide information below. The underside of sign the declaration but may not submit it directly to FDA. 21 CFR 314.53 (c)(4) and (d)(4). Check applicant/Holder MDA Applicant/Holder MDA Applicant/Holder's Attorney, Agent (Representative) or other Authorized Official Name Rex Mauthe, Vice President, Regulatory Affairs, United Therapeutics Corp Address 55 T.W. Alexander Drive Telephone Number (1919) 485-8350 FAX Number (# available) (919) 313-1298 This section applies only to requirements of the Paperwork Reluction Act of 1995. Do NOT SEND YOUR COMPLETED FORM TO THE FRA STAFF EMAIL ADDRESS BELOV- The winden time for this collection of information is estimated to average 5 hous per response, including the time to review instructions for the RDA specing but and solves accurately and complete and complete and preview the collection of information Stress Specing to review the collection o	ingredient) or the approved drug respect to which a claim of pater	product (formulation or compo t infringement could reasonable	osition) or appro	ved method(s) of use with a person not licensed by the	Yes	
supplement approved under section 505 of the Federal Food. Drug, and Cosmeire. Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. attest that I am familiar with 21 CFR 314.53 and this submission compiles 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. 8.2 Authorized Signature of NDA Applicant/Holder or Patent Owner (Attorney, Agent, Representative or other Authorized Official) (Provide information below) multified@unither.com Description of the State of the second of the State of the second of the State of the Authorized to sign the declaration below. NOTE: Only an NDA applicant/holder may submit this declaration directly to the FDA. A patent owner who is not the NDA applicant/holder is authorized to sign the declaration but may not submit the declaration directly to the STA. A patent owner who is not the NDA applicant/holder is authorized to sign the declaration but may not submit the directly to the CFR 314.53(c)(4) and (d)(4). Cheek applicable box and provide information below. Name Rex Mauthe, Vice President, Regulatory Affairs, United Therapeutics Corp Address 55 T.W. Alexander Drive [2] Pode [2] Pode [2] Pode [2] Pode [2] Pode [2] Pode [2] Pode [3] Potor SER YOUR COMPLETED FORM TO THE PRA State (available) [3] This section applies only to requirements of the Papervork Reduction Act of 1995. DO NOT SEND YOUR COMPLETED FORM TO THE PRA STATE FEMALL ADDRESS BLOW: The barden time for this collection of information is estimated to average 5 hours per response, including the time to review instructions, search estimating data sources; gather and maintain the data needed and complete and review the collection of information is estimated to average 5 hours per response, including the time to review instructions, search estimating data sources; gathere and maintain the data needed and completes and	6. Declaration Certification					
other Authorized Official) (Provide Information below) Difference on the construction of the constru	supplement approved u information is submitte complies with the requi correct.	Inder section 505 of the l d pursuant to 21 CFR 31 irements of the regulation	Federal Food, 4.53. I attest t n. I verify und	Drug, and Cosmetic Act. hat I am familiar with 21 Cl er penalty of perjury that t	This time-sensitive patent FR 314.53 and this submission he foregoing is true and	
mauth@unither.com Diffust instantion D6/08/2016 NOTE: Only an NDA applicant/holder may submit this declaration directly to the FDA. A patent owner who is not the NDA applicant/holder is autonized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53(c)(d) and (d)(d). Check applicable box and provide information below. Image: Check applicant/Holder			Owner (Attorney,	Agent, Representative or	Date Signed	
is authorized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53(c)(4) and (d)(4). Check applicable box and provide information below. Check applicable box and provide information below. Image: Check applicable box and provide information provide information applies only of the provide information is estimated on the provide information collection of information is estimated to average 5 hours per response, including the time to review instructions, search existing data sources, gather and maint in the data needed and complete and review the collection of information is estimated to average 5 hours per response, including the time to review instructions. Search existing data sources, gather and maint the data needed and complete and review the collection of information is estimated to average 5 hours per response, including the time to review instructions. Search existing data sources, gather and maint in the data needed and complete and review the collection of information is estimated to average 5 hours pe	rmauthe@unither.com			06/08/2016		
Image: Section applies only to requirements of the Paperwork Reduction Act of 1995. Image: Section applies only to requirements of the Paperwork Reduction Act of 1995. Image: Section of information. Send comments regarding this burden estimate to a varage 5 hours per response, including the time to review the collection of information. Send comments regarding this burden estimate to a varage 5 hours per response, including the time to review instructions, search existing data sources, gather and anianian the data needed and complete and review the collection of information Send comments regarding this burden estimate to a varage 5 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 to a varage 5 hours per response, including the time to review the collection of information forcer Paperwork (PALSugf@c/da.his.gor "An agency may not conduct or sponsor; and a person is not required to respond to, a collection of information officer Paperwork (PALSugf@c/da.his.gor						
Authorized Official Patent Owner Authorized Official Name Patent Owner's Attorney, Agent (Representative) or Other Authorized Official Name Rex Mauthe, Vice President, Regulatory Affairs, United Therapeutics Corp Address City/State S5 T.W. Alexander Drive City/State ZIP Code Telephone Number 27709 (919) 485-8350 FAX Number (if available) E-Mail Address (if available) (919) 313-1298 E-Mail Address (if available) This section applies only to requirements of the Paperwork Reduction Act of 1995. CO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFE EMAIL ADDRESS BELOW.+ The burden time for this collection of information is estimated to average 5 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, estimate or any other aspect of this information collection, including suggestions for reducing this burden, estimate or any other aspect of this information of a person is not required to respond to, a collection of information officer Paperwork Reduction Act (PRA) Starf Paperwork Reduction for tho	Check applicable box and prov	vide information below.				
Official Name Rex Mauthe, Vice President, Regulatory Affairs, United Therapeutics Corp Address 55 T.W. Alexander Drive ZiP Code 27709 (919) 485-8350 FAX Number (if available) (919) 313-1298 E-Mail Address (if available) (919) 313-1298 E-Mail Address (if available) rmauthe@unither.com 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 5 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 Officer Paperwork Reduction Act (PRA) Staff PLAStaff@[da.hhs.gov "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information Act (PRA) Staff PLAStaff@[da.hhs.gov	X NDA Applicant/	Holder			gent (Representative) or other	
Rex Mauthe, Vice President, Regulatory Affairs, United Therapeutics Corp Address 55 T.W. Alexander Drive S5 T.W. Alexander Drive City/State ZIP Code Research Triangle Park, North Carolina ZIP Code Telephone Number 27709 (919) 485-8350 FAX Number (if available) E-Mail Address (if available) (919) 313-1298 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 5 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 Chief Information Office of Chief Information Office of Chief Information Act (PRA) Staff PRAStaff@/da.hhs.gov "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information Act (PRA) Staff PRAStaff@/da.hhs.gov						
55 T.W. Alexander Drive Research Triangle Park, North Carolina ZIP Code Telephone Number 27709 (919) 485-8350 FAX Number (if available) E-Mail Address (if available) (919) 313-1298 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 5 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 Officer Chief Information Officer Papervork Reduction Act (PRA) Staff PARStaff@fda.hhs.gov "An agency may not conduct or sponsor, a collection of information officer Papervork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov	Rex Mauthe, Vice P	resident, Regulatory Affa	airs, United T			
27709 (919) 485-8350 FAX Number (if available) (919) 313-1298 E-Mail Address (if available) rmauthe@unither.com This section applies only to requirements of the Paperwork Reduction Act of 1995. The Support Section applies only to requirements of the Paperwork Reduction Act of 1995. The burden time for this collection of information is estimated to average 5 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 Chief Information Officer Paperwork Reduction Act (PRA) Staff PAAStaff@dda.hhs.gov "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information muless it displays a currently valid OMB number."		Drive			, North Carolina	
FAX Number (if available) (919) 313-1298 E-Mail Address (if available) rmauthe@unither.com 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 5 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 to: including suggestions for reducing this burden, to: Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 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 currently valid OMB number."	ZIP Code			Telephone Number		
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INFORMATION AND INSTRUCTIONS FOR FORM 3542

PATENT INFORMATION SUBMITTED UPON AND AFTER APPROVAL OF AN NDA OR SUPPLEMENT

General Information

- To submit patent information to the agency the appropriate patent declaration form must be used. Two forms are available for patent submissions. The approval status of your New Drug Application will determine which form you should use.
- Form 3542a should be used when submitting patent information with original NDA submissions, NDA amendments and NDA supplements prior to approval.
- Form 3542 should be used after NDA or supplement approval. This form is to be submitted within 30 days after approval of an application. This form should also be used to submit patent information relating to an approved supplement under 21 CFR 314.53(d) to change the formulation, add a new indication or other condition of use, change the strength, or to make any other patented change regarding the drug, drug product, or any method of use. Form 3542 is also to be used for patents issued after drug approval. Patents issued after drug approval are required to be submitted within 30 days of patent issuance for the patent to be considered "timely filed."
- Only information from form 3542 will be used for Orange Book publication purposes.
- Forms should be submitted as described in 21 CFR 314.53. Sending an additional copy of form 3542 to the Orange Book Staff will expedite patent publication in the Orange Book. The Orange Book Staff address (as of April 2007) is: Orange Book Staff, Office of Generic Drugs OGD/HFD-610, 7620 Standish Place, Rockville, MD 20855.
- The receipt date is the date that the patent information is date stamped in the central document room. Patents are considered listed on the date received.
- Additional copies of these forms may be downloaded from the Internet at: http://www.fda.gov/opacom/morechoices/fdaforms/ fdaforms.html.

First Section

Complete all items in this section.

1. General Section

Complete all items in this section with reference to the patent itself.

- 1c) Include patent expiration date, including any Hatch-Waxman patent extension already granted. Do not include any applicable pediatric exclusivity. The agency will include pediatric exclusivities where applicable upon publication.
- 1d) Include full address of patent owner. If patent owner resides outside the U.S. indicate the country in the zip code block.
- 1e) Answer this question if applicable. If patent owner and NDA applicant/holder reside in the United States, leave space blank.

2. Drug Substance (Active Ingredient)

Complete all items in this section if the patent claims the drug substance that is the subject of the approved NDA or supplement.

- 2.4) Name the polymorphic form of the drug identified by the patent.
- 2.5) A patent for a metabolite of the approved active ingredient may not be listed. If the patent claims an approved method of using the approved drug product to administer the metabolite, the patent may be listed as a method of use patent depending on the responses to section 4 of this form.
- Answer this question only if the patent is a product-byprocess patent.

3. Drug Product (Composition/Formulation)

Complete all items in this section if the patent claims the drug product that is the subject of the approved NDA or supplement.

3.3) An answer to this question is required only if the referenced patent is a product-by-process patent.

4. Method of Use

Complete all items in this section if the patent claims one or more methods of use of the drug product that is the subject of the approved NDA or supplement.

- 4.2) For each approved use of the drug claimed by the patent, identify by number the claim(s) in the patent that claim the approved use of the drug. An applicant may list together multiple patent claim numbers and information for each approved method of use, if applicable. However, each approved method of use must be separately listed within this section of the form.
- 4.2a) Identify the precise words of the approval labeling that describe with specificity the patented method of use.
- 4.2b) The answer to this question will be what FDA uses to create a "use-code" for Orange Book publication. The use code designates a method of use patent that claims an approved method of using a drug product. Each approved method of use claimed by the patent should be separately and specifically identified in this section and the use code created should contain adequate detail to assist 505(b)(2) and ANDA applicants in determining whether a listed method of use patent claims a method of use for which the 505(b)(2) or ANDA applicant is not seeking approval. Use a maximum of 240 characters for each "use code."

5. No Relevant Patents

Complete this section only if applicable.

6. Declaration Certification

Complete all items in this section.

6.2) Authorized signature. Check one of the four boxes that best describes the authorized signature.

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