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 NAME CAPPELCANTINDA HOLDER United Therapeutics Corp The following is provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act. TRADE NAME TVVASO STRENGTH(S) 0.6 mg/ml DOSAGE FORM Inhalation solution APPROVAL DATE OF NDA OR SUPPLEMENT July 30, 2009 STRENGTH(S) 0.6 mg/ml DOSAGE FORM Inhalation solution APPROVAL DATE OF NDA OR SUPPLEMENT July 30, 2009 STRENGTH(S) 0.6 mg/ml DOSAGE FORM Inhalation solution APPROVAL DATE OF NDA OR SUPPLEMENT July 30, 2009 STRENGTH(S) 0.6 mg/ml This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) within thirty (30) days after approval of an NDA or supplement or within thirty (30) days of issuance of a patent as required by 21 CFR 314 ASJ(44). To expedite review of the patent declaration form, you may submit an additional copy of this declaration form to the Center for Drug Evaluation and Research "Orange Book" staff. For hand-written or typewriter versions of this report. If additional space is required for any narrative answer (i.e., one that do not require a "Yei" or "No" esons), plasea attach an additional age referencing the question number. FDA will not list patent information if you file an incomplete patent declaration or the patent declaration indicates the pate is not eligible tor listing. For each patent submitted for the approved NDA or supplement referenced above, you must	Food and Drug Administ	nan Services tration		Ex	proved: OMB No. 0910-0513 piration Date: 10/31/2016
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FDA will not list patent information if you file an incomplete patent declaration or the patent declaration indicates the patent is not eligible for listing. For each patent submitted for the approved NDA or supplement referenced above, you must submit all the information described below. If you are not submitting any patents for this NDA or supplement, complete above section and sections and 6. 1. GENERAL a. United States Patent Number b. Issue Date of Patent c. Expiration Date of Patent y, 339,507 d. Name of Patent Owner United Therapeutics Corporation b. Traingle Park, North Carolin ZIP Code FAX Number (if available) (1919) 435-8350 mauthe@unither.com e. Name of agent or representative who resides or maintage to receive notics of patent endification under section 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 of NDA applicant/holder does not reside or heve a place of business within the United States) Address (if available) ZIP Code FAX Number (if available) City/State ZIP Code FAX Number (if available) ZIP Code City/State ZIP Code FAX Number (if available) 					
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9,339,507 May 17, 2016 March 10, 2028 d. Name of Patent Owner Address (of Patent Owner) United Therapeutics Corporation 55 T.W. Alexander Drive City/State Research Triangle Park, North Carolin ZIP Code FAX Number (if available) (919) 313-1298 Telephone Number E-Mail Address (if available) (919) 485-8350 e. 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- 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 place of business within the United States) Address (of agent or representative named in 1.e.) City/State City/State ZIP Code FAX Number (if available) Telephone Number E-Mail Address (if available) Telephone Number Yes No g. If the patent referenced above has been submitted previously for the sapproved NDA or supplement referenced above? Yes G. If the patent referenced above has been submitted previously for listing, is the expiration No	described below. If you are not submitting any				
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For the patent referenced above, provide the following information on each patent that claims to product, or method of use that is the subject of the approved NDA or supplement. FDA will not you file an incomplete patent declaration or the patent declaration indicates the patent is not el consider an incomplete patent declaration to be a declaration that does not include a response contained within each section below applicable to the patent referenced above.	list patent infi igible for listin	ormation if ng. FDA will
2. Drug Substance (Active Ingredient)		
2.1 Does the patent claim the drug substance that is the active ingredient in the drug product described in the approved NDA or supplement?	Yes	No No
2.2 Does the patent claim a drug substance that is a different polymorph of the active ingredient described in the NDA?	Ves	🔀 No
2.3 If the answer to question 2.2 is "Yes," do you certify that, as of the date of this declaration, you have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA? The type of test data required is described at 21 CFR 314.53(b).	Yes	□ No
2.4 Specify the polymorphic form(s) claimed by the patent for which you have the test results described in 2.3.		
2.5 Does the patent claim only a metabolite of the approved active ingredient? (Complete the information in section 4 below if the patent claims an approved method of using the approved drug product to administer the metabolite.)	Yes	🔀 No
2.6 Does the patent claim only an intermediate?	Yes	⊠ No
2.7 If the patent referenced in 2.1 is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	Yes	🗌 No
 the answer to 2.2 is "Yes" and the answer to 2.3 is "No," or, the answer to 2.3 is "Yes" and there is no response to 2.4, or, the answer to 2.5 or 2.6 is "Yes." the answer to 2.7 is "No." 		
3. Drug Product (Composition/Formulation)		
3.1 Does the patent claim the approved drug product as defined in 21 CFR 314.3?	🛛 Yes	□ No
3.2 Does the patent claim only an intermediate?	Yes	No No
3.3 If the patent referenced in 3.1 is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	Yes	□ No
 FDA will not list the patent in the Orange Book as claiming the drug product if: the answer to question 3.1 is "No," or, the answer to question 3.2 is "Yes," or, the answer to question 3.3 is "No." 		
4. Method of Use		
Sponsors must submit the information in section 4 for each approved method of using the approved drug p For each approved method of use claimed by the patent, provide the following information:	product claimed	d by the patent.
4.1 Does the patent claim one or more approved methods of using the approved drug product?	Yes	⊠ No
4.2 Patent Claim Number(s) (as 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. Use: (Submit indication or method of use information as identified specifically in the specific reference to the drug product. 	the approved lab	Page 2

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4.2b If the answer to 4.2 is "Yes," also provide the information on the indication or method of use for the Orange Book "Use Code" description.			d indication or method of use t o more than 240 total characte	hat you propose FDA include as ars including spaces.)	
FDA will not list the patent in t		ng the method of	use if:		
 the answer to question if the answer to 4.2 is " 	-	equested in 4.2a	and 4.2b is not provided in f	ull.	
5. No Relevant Patents		-			
For this NDA or supplement, the ingredient) or the approved drug respect to which a claim of pater owner of the patent engaged in t	product (formulation or com t infringement could reason	position) or appro ably be asserted it	ved method(s) of use with a person not licensed by the	☐ Yes	
6. Declaration Certification					
information is submitte complies with the requ correct.	d pursuant to 21 CFR 3 irements of the regulation	14.53. I attest t on. I verify und	hat I am familiar with 21 C	This time-sensitive paten CFR 314.53 and this submi the foregoing is true and C. 1001.	
6.2 Authorized Signature of ND		Owner (Attorney,	Agent, Representative or	Date Signed	
other Authorized Official) (P	rovide Information below)	er.com	signed by mauthe@unither.com mauthe@unither.com, authe@unither.com 10.05.17 13:39:54 -04'00'	05/17/2016	
NOTE: Only an NDA applicant is authorized to sign the decla					
Check applicable box and pro	vide information below.				
🔀 NDA Applicant	Holder		Applicant's/Holder's Attorney,	Agent (Representative) or othe	
Patent Owner	Patent Owner's Attorney, Agent (Representative) or Other Authorize Official				
Name					
Address	sident Regulatory Affairs		City/State		
55 T.W. Alexander Di	B W. Alexander Drive		Research Triangle Park, North Carolin		
ZIP Code			Telephone Number		
27709			(919) 485-8350		
FAX Number <i>(if available)</i> (919) 313-1298			E-Mail Address (if available) rmauthe@unither.com		
The burden the review instruct collection of in	OT SEND YOUR COMPLET ne for this collection of infor- tions, search existing data so	TED FORM TO TH mation is estimated urces, gather and r garding this burden	he Paperwork Reduction Act of 19 HE PRA STAFF EMAIL ADDR to average 5 hours per response maintain the data needed and co estimate or any other aspect of thi	RESS BELOW.* e, including the time to omplete and review the	
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	d authenticated cour	t documents	without watermarks a	at <u>docketalarm.com</u> .	

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.

FORM FDA 3542 (11/13)

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