CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 22-363

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

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 (Active Ingredient), Drug Product (Formulation and Composition) and/or Method of Use Form Approved: OMB No. 0910-0513 Expiration Date: 04/30/10 See OMB Statement on Page 3.

NDA NUMBER

22-363

NAME OF APPLICANT / NDA HOLDER

Kowa Company Limited

,	200 Jan 2000-			
The following is provided in accordance with	Section 505	i(b) and (c) of the Federal F	ood, Drug, and Cosmetic Act.	
TRADE NAME (OR PROPOSED TRADE NAME) Livalo (proposed)				
ACTIVE INGREDIENT(S) Pitavastatin Calcium		STRENGTH(S) 1 mg, 2 mg, 4 mg		
DOSAGE FORM Tablet, Oral				
This patent declaration form is required to be submanendment, or supplement as required by 21 CFR 314.53 Within thirty (30) days after approval of an NDA or sudeclaration must be submitted pursuant to 21 CFR 37 or supplement. The information submitted in the declaration by FDA for listing a patent in the Orange Book.	at the addres pplement, or 14.53(c)(2)(ii)	s provided in 21 CFR 314.53(o within thirty (30) days of is with all of the required inf	d)(4). suance of a new patent, a new patent ormation based on the approved NDA	
For hand-written or typewriter versions (only) of that does not require a "Yes" or "No" response), please	attach an ac	ditional page referencing the	question number.	
FDA will not list patent information if you file at patent is not eligible for listing.	n incomple	te patent declaration or t	he patent declaration indicates the	
For each patent submitted for the pending NDA, information described below. If you are not submounded above section and sections 5 and 6.				
1. GENERAL	dvistraji Ti Danvissa			
a. United States Patent Number 5,854,259	b. Issue Da Dec. 29	ate of Patent , 1998	c. Expiration Date of Patent Dec. 29, 2015	
d. Name of Patent Owner Nissan Chemical Industries, Ltd.		Patent Owner) -Nishiki-Cho 3-Chome, Chiyoda	a-Ku	
	City/State Tokyo, Japa	an		
	ZIP Code		FAX Number (if available) 81-3-3296-8332	
	Telephone 81-3-3296-		E-Mail Address (if available) otam@nissanchen.co.jp	
e. Name of agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section	Address (of agent or representative named in 1.e.) 430 Davis Drive Suite 200			
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)	City/State Morrisville	y/State orrisville, NC 27560		
Kowa Research Institue, Inc. Attn: Ross Laderman MPH	ZIP Code 27560		FAX Number (if available) 919 433 1620	
Agent for Kowa Company Limited	Telephone 919 433 16	00	E-Mall Address (if available) rladerman@kowaus.com	
f. Is the patent referenced above a patent that has been subnapproved NDA or supplement referenced above?			☐ Yes ⊠ No	
g. If the patent referenced above has been submitted previous date a new expiration date?	sly for listing, i	s the expiration	☐ Yes ☐ No	

	the patent referenced above, provide the following information on the drug substance, that is the subject of the pending NDA, amendment, or supplement.	drug product	and/or method of
2. D	rug Substance (Active Ingredient)		
	Does the patent claim the drug substance that is the active ingredient in the drug product described in the pending NDA, amendment, or supplement?	Yes	⊠ No
2.2	Does the patent claim a drug substance that is a different polymorph of the active ingredient described in the pending NDA, amendment, or supplement?	Yes	⊠ 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.		
t.			
2.5	Does the patent claim only a metabolite of the active ingredient pending in the NDA or supplement? (Complete the Information in section 4 below if the patent claims a pending method of using the pending 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
3. E	Drug 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 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
4 N	Method of Use		
Spc	onsors must submit the information in section 4 for each method of using the pending drug product t is claimed by the patent. For each pending method of use claimed by the patent, provide the following		roval is being sought
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	⊠ No
4.2	Patent Claim Number(s) (as listed in the patent) Does (Do) the patent claim(s) referenced in 4.2 claim a pending method of use for which approval is being sough in the panding NDA amondment or supplement?	L	
4.2	in the pending NDA, amendment, or supplement? a If the answer to 4.2 is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product. Use: (Submit indication or method of use information as identified specifically in the pending NDA, amendment, or supplement? Use: (Submit indication or method of use information as identified specifically in the pending NDA, amendment, or supplement?	L Yes the approved lat	∟ No peling.)
5. N	No Relevant Patents		
drug whi	this pending NDA, amendment, or supplement, there are no relevant patents that claim the drug substance (are g product (formulation or composition) or method(s) of use, for which the applicant is seeking approval and with characteristic action of patent infringement could reasonably be asserted if a person not licensed by the owner of the patential manufacture, use, or sale of the drug product.	h respect to	Yes

FORM FDA 3542a (7/07) Page 2

6. Declaration Certification							
6.1 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 time-sensitive 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.							
Warnir	Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.						
6.2 Authoriz other Au	6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner (Attorney, Agent, Representative or other Authorized Official) (Provide Information below) Date Signed 10/1/2008						
	an NDA applicant/holder may submit this horized to sign the declaration but may not su						
Check applic	cable box and provide information below.						
·· .	☐ NDA Applicant/Holder		DA Applicant's/Holder's Attorney, thorized Official	Agent (Representative) or other			
	Patent Owner		stent Owner's Attorney, Agent (R	epresentative) or Other Authorized			
Name Kowa	Research Institue, Inc.						
Addres 430 D	ss avis Drive Suite 200		City/State Morrisville, NC 27560				
ZIP Co 27560			Telephone Number 919 433 1600				
	FAX Number (if available) 919 433 1620 E-Mail Address (if available) rladerman@kowaus.com						
The public reporting burden for this collection of information has been estimated to average 20 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Food and Drug Administration CDER (HFD-007) 5600 Fishers Lane Rockville, MD 20857 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 control number.							

Department of Health and Human Services Food and Drug Administration

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TRADE NAME (OR PROPOSED TRADE NAME) Livalo (proposed)					
ACTIVE INGREDIENT(S)		STRENGTH(S)			
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DOSAGE FORM Tablet, Oral					
This patent declaration form is required to be submit amendment, or supplement as required by 21 CFR 314.53.2 Within thirty (30) days after approval of an NDA or sup declaration must be submitted pursuant to 21 CFR 31 or supplement. The information submitted in the declar upon by FDA for listing a patent in the Orange Book.	at the addrest oplement, or 4.53(c)(2)(ii) ation form	s provided in 21 CFR 314.53(c within thirty (30) days of iss with all of the required info submitted upon or after appro-	i)(4). suance of a new patent, a new patent ormation based on the approved NDA oval will be the only information relied		
For hand-written or typewriter versions (only) of that does not require a "Yes" or "No" response), please	his report: attach an ac	If additional space is required it is in additional page referencing the	ed for any narrative answer (i.e., one question number.		
FDA will not list patent information if you file ar patent is not eligible for listing.	n incomple	te patent declaration or to	he patent declaration indicates the		
For each patent submitted for the pending NDA, information described below. If you are not submomplete above section and sections 5 and 6.	amendmen nitting any	t, or supplement reference patents for this pending	ed above, you must submit all the NDA, amendment, or supplement,		
1. GENERAL					
a. United States Patent Number 5,856,336	b. Issue Da Jan. 5, 1	ate of Patent 999	c. Expiration Date of Patent Jan. 5, 2016		
d. Name of Patent Owner Nissan Chemical Industries, Ltd.	Address <i>(of Patent Owner)</i> 7-1, Kanda-Nishiki-Cho 3-Chome, Chiyoda-Ku				
	City/State				
	Tokyo, Japa	an			
" the white	ZIP Code		FAX Number (if available)		
	ZIF Code		81-3-3296-8332		
*	Telephone		E-Mail Address (if available)		
- \$\display \tau \text{Price} - \display \tau \text{Price}	81-3-3296-	8365	otam@nissanchen.co.jp		
e. Name of agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the Federal Food, Drug, and	4	agent or representative named in Drive Suite 200	in 1.e.)		
Cosmetic Act and 21 CFR 314.52 and 314.95 (if patent	City/State				
owner or NDA applicant/holder does not reside or have a place of business within the United States) Morrisville, NC 27560					
Kowa Research Institue, Inc.	ZIP Code		FAX Number (if available)		
Attn: Ross Laderman MPH	27560		919 433 1620		
Agent for Kowa Company Limited	Telephone		E-Mail Address (if available)		
	919 433 16	00	rladerman@kowaus.com		
f. Is the patent referenced above a patent that has been submapproved NDA or supplement referenced above?	ltted previous	sly for the	☐ Yes No		
g. If the patent referenced above has been submitted previous	ly for listing, i	s the expiration			
date a new expiration date?		-	☐ Yes ☐ No		

Drug Substance (Active Ingredient)		
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drug product to administer the metabolite.)	Yes	⊠ No
6 Does the patent claim only an intermediate?	_	_
to the state of th		
	Yes	⊠ No
.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
AND THE PROPERTY OF THE SECOND PORT AND A RESIDENCE OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY AND THE	Yes	
patent novel? (An answer is required only if the patent is a product-by-process patent.)		☐ No
patent novel? (An answer is required only if the patent is a product-by-process patent.) • Drug Product (Composition/Formulation)	Yes	
patent novel? (An answer is required only if the patent is a product-by-process patent.) Drug:Product (Composition/Formulation) 1 Does the patent claim the drug product, as defined in 21 CFR 314.3, in the pending NDA,	Yes	□ No ☑ No
patent novel? (An answer is required only if the patent is a product-by-process patent.) Drug Product (Composition/Formulation) Does the patent claim the drug product, as defined in 21 CFR 314.3, in the pending NDA, amendment, or supplement?	Yes	☐ No
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FORM FDA 3542a (7/07)

6. De	6. Declaration Certification					
6.1 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 stateme	ent is a crir	ninal offense under 18 U.S.C.	1001.		
58	6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner (Attorney, Agent, Representative or other Authorized Official) (Provide Information below) Date Signed 10/01/2008					
NOT	E: Only an NDA applicant/horder may submit this or is authorized to sign the declaration but may not su	declaration bmit it direc	directly to the FDA. A patent of tly to FDA. 21 CFR 314.53(c)(4) an	owner who is not the NDA applicant/ nd (d)(4).		
Chec	ck applicable box and provide information below.					
	☐ NDA Applicant/Holder	\boxtimes	NDA Applicant's/Holder's Attorney Authorized Official	, Agent (Representative) or other		
	Patent Owner		Patent Owner's Attorney, Agent (R Official	tepresentative) or Other Authorized		
	Name Kowa Research Institue, Inc.					
	Address 430 Davis Drive Suite 200 City/State Morrisville, NC 27560					
	ZIP Code 27560		Telephone Number 919 433 1600			
	FAX Number (if available) 919 433 1620	FE (4)	E-Mail Address (if available) rladerman@kowaus.com	# # # # # # # # # # # # # # # # # # #		
searc	public reporting burden for this collection of information has bee hing existing data sources, gathering and maintaining the data no en estimate or any other aspect of this collection of information,	eded, and con	npleting and reviewing the collection of estions for reducing this burden to:			
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	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 control number.					
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Department of Health and Human Services Food and Drug Administration

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

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For each patent submitted for the pending NDA, information described below. If you are not submounted above section and sections 5 and 6.					
1. GENERAL					
a. United States Patent Number 6,465,477	b. Issue Date Oct. 15, 200		c. Expiration Date of Patent Dec. 20, 2016		
d. Name of Patent Owner Kowa Company Limited and Nissan Chemical Industries, Ltd	Address (of Par 6-29, Nishiki 3	ent Owner) -Chome, Naka-Ku, Nagoya-	Shi		
The state of the s	City/State Aichi, Japan				
	ZIP Code	*	FAX Number (if available) 81-3-327-7589		
	Telephone Nun 81-3-3279-736		E-Máil Address (if available) yotakahs@kowa.co.jp		
e. Name of agent or representative who resides or maintains. Address (of agent or representative named in 1.e.) a place of business within the United States authorized 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)	City/State Morrisville, No	C 27560			
Kowa Research Institue, Inc. Attn: Ross Laderman MPH	ZIP Code 27560		FAX Number (if available) 919 433 1620		
Agent for Kowa Company Limited	Telephone Nur 919 433 1600	nber	E-Mail Address (if available) rladerman@kowaus.com		
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described in the NDA? The type of test data required is described at 21 CFR 314.53(b).	Yes	∐No
4 Specify the polymorphic form(s) claimed by the patent for which you have the test results described in 2.3.		
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		,
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ponsors must submit the information in section 4 for each method of using the pending drug prod		
	ung imormation	: ⊠ No
that is claimed by the patent. For each pending method of use claimed by the patent, provide the follow. 1 Does the patent claim one or more methods of use for which approval is being sought in	Von	Ø 140
 nat is claimed by the patent. For each pending method of use claimed by the patent, provide the follow 1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement? 2 Patent Claim Number(s) (as listed in the patent) Does (Do) the patent claim(s) referenced in 4.2 claim 		
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6. D	eclaration Certification						
6.1							
6.2	6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner (Attorney, Agent, Representative or other Authorized Official) (Provide Information below) Date Signed 10/1/2008						
	E: Only an NDA applicant/holder i er is authorized to sign the declarati				t owner who is not the NDA applicant/ and (d)(4).		
Che	ck applicable box and provide inform	nation below.					
	☐ NDA Applicant/Holder	* *** *** *** ******		NDA Applicant's/Holder's Attorn Authorized Official	ey, Agent (Representative) or other		
	Patent Owner	en e	ra ta ta t	Patent Owner's Attorney, Agent Official	(Representative) or Other Authorized		
	Name Kowa Research Institue, Inc.	er to take o		*			
	Address 430 Davis Drive Suite 200	ne to the experience.		City/State Morrisville, NC 27560			
	ZIP Code 27560	;		Telephone Number 919 433 1600			
	FAX Number (if available) 919 433 1620	199 × 194 9	nana Ngalantha	E-Mail Address (if available rladerman@kowaus.com)		
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