CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

021446Orig1s028

ENVIRONMENTAL ASSESSMENT

Environmental Assessment
Finding of No Significant Impact

NDA 21-446/S-028
Lyrica (Pregabalin) Capsules

Food and Drug Administration
Center for Drug Evaluation and Research

May 16, 2012

FINDING OF NO SIGNIFICANT IMPACT

NDA 21-446/S-028

Lyrica® (Pregabalin) Capsules

The National Environmental Policy Act of 1969 (NEPA) requires all Federal agencies to assess the environmental impact of their actions. The Food and Drug Administration (FDA) is required under NEPA to consider the environmental impact of approving certain drug product applications as an integral part of the regulatory process.

NDA 21-446/S-028 requests approval for Lyrica® (Pregabalin) Capsules. This NDA is intended to expand the use of Lyrica® (Pregabalin) for use as an analgesic agent for management of central neuropathic pain secondary to spinal cord injury. In support of its application, Pfizer, Inc., prepared an environmental assessment (attached) in accordance with 21 CFR Part 25, which evaluates the potential environmental impacts of Lyrica® (Pregabalin).

The Food and Drug Administration, Center for Drug Evaluation and Research, has carefully considered the potential environmental impact due to approval of this application and has concluded that this action is not expected to have a significant impact on the environment. Therefore, an environmental impact statement will not be prepared.

PREPARED BY:

Raanan A. Bloom, Ph.D. Senior
Environmental Officer Office of
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CONCURRED BY:

Nakissa Sadrieh, Ph.D.
Associate Director for Research Policy and Implementation
Office of Pharmaceutical Science

Attachment: November 18, 2011, Environmental Assessment

ENVIRONMENTAL ASSESSMENT

NON-CONFIDENTIAL [FREEDOM OF INFORMATION ACT (FOIA)] SUBMISSION

Lyrica®

Pregabalin for Use in the Management of Central Neuropathic Pain due to Spinal Cord Injury

Supplement to NDA No. 21-446

November 2011

Pfizer Inc
235 East 42nd Street
New York, NY 10017

ENVIRONMENTAL ASSESSMENT

SUMMARY

The applicant certifies that the Environmental Assessment (EA) provided in support of Lyrica® capsules (NDA No. 21-446; Finding of No Significant Impact) is valid for this supplemental NDA. Pfizer anticipates no adverse effects to environmental organisms as a result of excreted pregabalin entering into publicly owned treatment works (POTWs) and subsequent release environments.

1. DATE: 18 November 2011

2. NAME OF APPLICANT: Pfizer Inc

3. ADDRESS: 235 East 42nd Street, New York, NY 10017

4. DESCRIPTION OF PROPOSED ACTION:

a. RequestedApproval: Pfizer Inc has submitted a supplemental NDA pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act for pregabalin as an analgesic agent for management of central neuropathic pain associated with spinal cord injury. The pregabalin sNDA includes capsules containing 150, 200, 225, and 300 mg pregabalin, which are packaged in HDPE bottles and PVC/foil blisters. An EA is being submitted pursuant to 21 CFR Part 25, following the Center for Drug Evaluation and Research, "Guidance for Industry Environmental Assessment of Human Drug and Biologics Applications," dated July 1998.[1]

b. NeedfortheAction: Pregabalin is an analogue of the mammalian neurotransmitter, γ-amino butyric acid (GABA) and has been approved for the chronic pain (neuropathic pain), treatment of fibromyalgia, and management of epilepsy and generalized anxiety disorder. Pregabalin is marketed as Lyrica® in the United States. In addition to its currently approved uses, pregabalin has demonstrated efficacy in the management of central neuropathic pain associated with spinal cord injury.

c. LocationsofUse: Pregabalin will be used as a prescription agent in home and hospital environments throughout the US.

d. DisposalSites: End-user disposal of empty or partially empty packages at US hospitals, pharmacies, and clinics will follow hospital, pharmacy, or clinic procedures. Empty or partially empty containers in residences will typically be disposed of by a community's solid waste management system, which may include landfills, incineration, and/or recycling. Minimal quantities of unused drug may be disposed to sewer or septic systems.

5. IDENTIFICATION OF CHEMICAL SUBSTANCES THAT ARE SUBJECT OF THE PROPOSED ACTION

a. Nomenclature

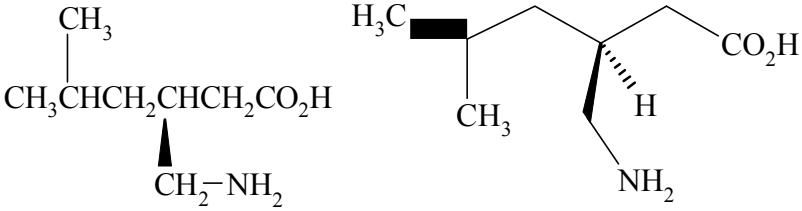
i. Established Name (USAN): pregabalin
ii. Tradename: Lyrica®
iii. Chemical Name: (S)-3-(Aminomethyl)-5-methylhexanoic acid

b. Chemical Abstracts Service (CAS) Registration Number: 148553-50-8

c. Molecular Formula: $C_8H_{17}NO_2$

d. Molecular Weight: 159.23

e. Structural Formula:



Structural Formula Stereochemical Formula

6. ENVIRONMENTAL ISSUES

This EA focuses on the fate and effects of the active moiety pregabalin, for which the estimated concentration in the aquatic environment is projected to exceed 1 ppb at the point of entry. A tiered approach to testing was used. The physical-chemical, fate, and ecotoxicity protocols used in testing pregabalin followed the Technical Assistance Documents (TAD) as published in FDA's EA Technical Assistance Handbook and OECD (Organization for Economic Co-Operation and Development) Test Guidelines.

a. Environmental Fate of Released Substances

i. Identification of Substance of Interest

- Pregabalin is mainly excreted in the urine (92% of the oral dose). Of the excreted amount, 89% is excreted as unchanged pregabalin with an additional 0.9% identified as an N-methylated derivative of pregabalin.[2] Pregabalin is the primary entity released into the environment and is therefore a valid environmental tracer for assessing fate and effects. Pregabalin will reside mainly in the aquatic compartment, as described in Section 6.a.v.

ii. Physical and Chemical Characterization

Refer to the Data Summary Table (Appendix 1) for a review of physical-chemical data for pregabalin.

- Dissociation Constant - Two pKa values were determined for pregabalin, 4.2 for the carboxyl group and 10.6 for the amine. Pregabalin will therefore exist as a zwitterion at environmental pH's.

- Solubility- The solubility of pregabalin ranges from 47 mg/mL at pH 10.1 to 107 mg/mL at pH 3.7. At pH <3.7, pregabalin mainly exists as a cation and is considered freely soluble.

- Octanol/ Water Partition Coefficient- Based on the log K_{ow} value of -1.35 at pH 7.4, pregabalin is not likely to partition into lipid based tissues or organic matter in the environment.

- Vapor Pressure (Vp estimate) - $<1 \times 10^{-7}$ mm Hg at 25°C. Vapor pressure estimates are based on the group and bond contribution methods of Hine and Mookerjee.[3] Pregabalin is not volatile and therefore would not enter the air compartment.

- Based on the experimentally determined K_d sludge value of 13.3, pregabalin is unlikely to significantly sorb to particulate matter, humic acids, and sediments.

iii. Environmental Depletion Mechanisms

- Based on the criteria defined in the Guidance for Industry document, pregabalin will not rapidly deplete in the aquatic environment by sorption, biodegradation, hydrolysis, or photolysis. Refer to Data Summary Table (Appendix 1) for an overview of depletion mechanism data for pregabalin.
- Wastewater Treatment Removal - Wastewater treatment will result in a mean of 2.3% removal through sorption to waste solids and a mean of 1.7% removal through mineralization to CO_2. Ninety-six percent of drug will be eliminated through effluent either as unchanged drug or as the biotransformed N-acetylated degradation product (14%).

- Sorption- Once in the water compartment, pregabalin is not expected to significantly sorb to particulate matter, humic acids, suspended sediments, and sediments due to its low K_d sludge value, high solubility and small molecular size. Less than 35% was found to be irreversibly bound to sediments in OECD 308 water-sediment biodegradation study.

- Hydrolysis- Formal hydrolysis experiments were not conducted as pregabalin has no constituents capable of being hydrolyzed. Based on the

Guidance for Industry's hydrolysis rapid depletion criteria of t½ ≤24 hours, pregabalin will not deplete by this mechanism.

- Water-Sediment Biodegradation- Up to 31% was observed to be mineralized at end of 103 days in OECD 308 water-sediment biodegradation study. Total system half lives for pregabalin ranged from 55.9 to 94.9 days.

- Chemical Depletion (lactamization)- Pregabalin is essentially an amino acid. The main degradation pathway, although minimal, is lactamization. Based on the demonstrated degradation of pregabalin to lactam at approximately pH 4 and pH 10, there is a potential for pregabalin to slowly deplete at environmental pH's. Refer to Section 3.2.S.7.3.4 Stability Data Tables for additional stability data.

Exposure Conditions	% Pregabalin (w/w)	% Lactam (w/w)
0.1N HCL, 80°C, 24 hours	94.9	3.3
0.1N NaOH, 80°C, 6 hours	81.8	15.0

- Photolysis- The ultraviolet spectra of pregabalin, as determined in aqueous media, demonstrate no absorption above 250 ηm. With no chromophore present, normal mechanisms for photodegradation in the environment are not likely to apply.

- BCF- Potential bioconcentration in the food chain is not a concern as the partition coefficient of pregabalin is well below a Log D value of 3 at environmentally relevant pH's.

iv. Environmental Concentrations

(1) Expected Introduction Concentration (EIC):

$EIC_{aquatic}$ (ppm) = A × B × C × D

Where: A = kg/yr produced for direct use (Confidential Appendix 1).
B = 1/L/day entering POTWs*.
C = years/365 days.
D = 1×10^6 mg/kg (conversion factor).

*1.22×10^{11} L/day entering POTWs (2008 Clean Water Needs Survey)

The EIC entering the external aquatic environment ($EIC_{aquatic}$) from POTWs has been calculated (Confidential Appendix 3). The calculations are based on

total pregabalin peak usage (see Confidential Appendix 2) as a conservative estimate. Pregabalin usage projections (including incremental use projected from this supplemental filing) show no increase usage over current peak usage level. No adjustments have been made to account for metabolism, other environmental depletion mechanisms, or for the dilution of wastewater effluents into the receiving waters.

(2) Expected Environmental Concentration (EEC):

The Expected Environmental Concentration (EEC), which is sometimes referred to as the Predicted Environmental Concentration (PEC), is calculated as follows:

$$PEC = EIC_{aquatic} \times [(100 - R)/(100 \times DF)]$$

Where: %Removal (R) = 0.24.
Dilution Factor (DF) = 10.

The PEC refines the original EIC estimate by accounting for removal on sludge during wastewater treatment and subsequent dilution into the receiving waters. The PEC was calculated using 0.24% for removal on sludge, based on an experimentally determined sludge sorption coefficient (K_d), and a dilution factor of 10 for dilution of waste water effluents into receiving waters (Confidential Appendix 4).

v. Summary

Pregabalin will enter the aquatic environment through effluents discharged by POTWs. Pregabalin is not volatile and therefore will not enter the air compartment. As noted in the Guidance for Industry document, generally, only a fraction of sludge from POTWs would be applied to soil. Based on the K_d sludge for pregabalin, sludge applied to land would not result in a significant concentration of pregabalin in the soil compartment. Based on these environmental transport considerations, and an assessment of the physical-chemical properties, pregabalin will reside in the aquatic compartment. Consequently, environmental effects data were generated on aquatic species.

Pregabalin is not anticipated to be rapidly removed from the aquatic compartment through the depletion mechanisms of sorption, biodegradation, hydrolysis, and photolysis. Its removal from the environment results from microbial biotransformation and chemical degradation. Pregabalin shows considerable mineralization and biotransformation in the water-sediment system. Based on the stability data, there is also a potential for pregabalin to slowly degrade in the environment through lactamization.

b. **Environmental Effects of Released Substances**

i. Microbial Inhibition Testing- The microbial inhibition concentration (MIC) for all microorganisms and activated sludge tested is >997 mg/L. Based on these data, pregabalin has no significant potential to inhibit microorganisms, and therefore, would not disrupt wastewater treatment processes. Refer to Data Summary Table (Appendix 1).

ii. Tiered Ecotoxicity Testing- Based on the acute and chronic data provided in the original NDA, the chronic ecotoxicity data are used to determine the effect of pregabalin on the environment. Refer to the Data Summary Table (Appendix 1) for review of effects data for pregabalin.

iii. Predicted No Effect Concentration (PNEC)

The PNEC is calculated by applying an assessment factor (AF) to the effects data developed in the tiered testing; where

PNEC = NOEC or $L(E)C_{50}/AF$

The PNEC for pregabalin was calculated using the standard tier 3 assessment factor of 10. The PNEC is based on the fathead minnow, the most sensitive species. The PNEC for pregabalin is 0.1 mg/L as calculated in Appendix 5, (Confidential).

iv. Summary

The ecotoxicity of pregabalin to 3 aquatic species was investigated for both acute and chronic endpoints; and investigated for 1 sediment species for chronic endpoints. Based on these data, fathead minnow was determined to be the most sensitive environmental organism and was therefore used to determine the PNEC for the aquatic environment. For each species tested, the No Observable Effect Concentration (NOEC) is >1 mg/L and significantly greater than the EIC. It is therefore anticipated that pregabalin would not have an adverse affect on the environment.

c. Summary

Upon approval of the subject NDA, introduction of pregabalin into the environment through use and disposal by consumers is projected to result in an insignificant amount of pregabalin in the environment. Based on the PEC/PNEC risk assessment, it is unlikely that pregabalin represents a risk to the aquatic environment. The PEC/PNEC risk assessment for total pregabalin usage is based on fathead minnow, the most sensitive species tested. This risk assessment was conducted using a conservative estimate for the PEC. No adverse environmental effect was identified in this assessment, as demonstrated by a calculated PEC/PNEC ratio of approximately 3 orders of magnitude <1.0, the threshold of concern. The PEC/PNEC risk assessment based on pregabalin usage is provided in Confidential Appendix 5.

Analysis of current data provides that "No Further Action" is required since the PEC/PNEC is significantly <1.0 and the fathead minnow NOEC is substantially more than the EIC.

7. MITIGATION MEASURES

No adverse environmental effects have been identified. No mitigation measures are required.

8. ALTERNATIVES TO THE PROPOSED ACTION

No potential effects have been identified for this proposed action. No alternatives to the proposed action are required.

9. LIST OF PREPARERS

Jon F. Ericson: Associate Research Fellow, Environmental Sciences/ Pharmacokinetics, Dynamics and Metabolism, Pfizer World Wide Research and Development, Groton, CT USA.

Associate Research Fellow with 25 years at Pfizer; 18 years experience with Environmental Risk Assessments and seven years in Animal Health Drug Metabolism. Lead in environmental fate R&D with extensive experience in ERA regulatory documentation, analytical methods development, data analyses, and outsourcing GLP studies. Active in SETAC, ECETOC, DIA, INFORMA and PhRMA activities.

CERTIFICATION

The undersigned certifies that the information presented is true, accurate, and complete to the best of Pfizer Inc's knowledge.

Jon F. Ericson	Associate Research Fellow, Environmental Sciences/ Pharmacokinetics, Dynamics & Metabolism Pfizer World Wide Research and Development, Groton, CT 06340 USA

10. REFERENCES

1. Guidance for Industry Environmental Assessment of Human Drug and Biologics Applications. Center for Drug Evaluation and Research (CDER). Jul 1998.

2. "A Study of the Mass Balance and Metabolism of [^{14}C] CI-1008 (Pregabalin) in Healthy Volunteers: Protocol 1008-5," Total Renal Pharmaceutical Research Institute, Inc, Feb 2000.

3. "Hine J, Mookerjee PK. "The Intrinsic Hydrophilic Character of Organic Compounds. Correlations in Terms of Structural Contributions," *J. Org. Chem*. 1975;40:292-98 (Available upon request).

4. Dias FF, Alexander M. Effect of Chemical Structure on the Biodegradability of Aliphatic Acids and Alcohols. Applied Microbiology 1971, 22, 1114-8.

11. APPENDICES

Nonconfidential

1. Data Summary Tables

Confidential.

2. Projected Total Usage

3. Basis for Expected Introduction Concentration (EIC) From Use Into the External Aquatic Environment

4. Basis for Predicted Envionmental Concentration (PEC) or Expected Environmental Concentration (EEC) From Use Into the External Aquatic Environment

5. Basis for PEC/PNEC Calculation and Decision Criteria for 'Stop' No Further Action

6. 2438.6572; "Pregabalin- Aerobic Transformation in Aquatic Sediment Systems", Following OECD Guideline 308

7. 2438.6576; "Pregabalin- Determination of Activated Sludge Respiration Inhibition", Following OECD Guideline 209

8. 2438.6526; "Pregabalin- Early Life-Stage Toxicity Test with Fathead Minnow, (*Pimephales promelas*)", Following OECD Guideline 210

9. 2438.6553; "Pregabalin- Full Life-Cycle Toxicity Test with Sediment-Dwelling Midges *(Chironomus riparius)* under Static Conditions", Following OECD Guideline 218

NONCONFIDENTIAL APPENDIX

Appendix 1. Data Summary Tables

Physical-Chemical Characterization			
Melting Point	190ºC		
Ultraviolet-Visible Spectrum	**Extinction Coefficient (L/mol-cm)**		
194 nm	256		
207 nm	40.1		
216 nm	44.2		
Water Solubility	**(mg/mL)**		
pH 3.7	107		
pH 7.4	32		
pH 10.1	47		
Dissociation Constant (pKa)	4.2 (carboxyl group)		
	10.6 (amine)		
Octanol/Water Partition Coefficient	**(log K_{ow})**		
pH 1	-1.90		
pH 4	-1.43		
pH 7.4	-1.35		
Sorption Coefficient	**ID**	**K_d**	**K_{oc}**
Activated Sludge	---	13.3	41.6
Soil	DU	3.97	105
	MT	0.99	110
	MSL	1.44	79.8
	SP	1.25	57.9

Data Summary Tables (continued)

Depletion Mechanisms		
Hydrolysis at Environmental Conditions	Stable	
Photolysis: Half life (days)	NA	
Aerobic Sludge Biodegradation	-2.19% after 28 days	
Chemical Depletion (lactamization)	% pregabalin (w/w)	% lactam (w/w)
0.1N HCL, 80ºC, 24 hours	94.9	3.3
0.1N NaOH, 80ºC, 6 hours	81.8	15.0
Porous Pot (wastewater treatment simulation)	2.3 % removal sludge	
	1.7 % mineralization (CO_2 production)	
	14% biotransformed to N-acetylated product	
Water-Sediment Biodegradation[6]	Aqueous Dissipation Half Life: 37.1- 68.6 days	
	Total System Half Life: 55.9- 94.9 days	
	Mineralization: 22.7- 31%	
	% Bound @ day 103: 11.7- 35.2%	

Data Summary Tables (continued)

Environmental Effects		
PREGABALIN		
	(mg/L(Kg))	
Microbial Inhibition (MIC)		
Aspergillus niger (mold)	>1000	
Trichoderma viride (fungus)	>1000	
Clostridium perfringens (nitrogen-fixing bacteria)	>997	
Bacillus subtilis (soil bacteria)	>1000	
Nostoc sp. (blue-green algae)	>1000	
Sludge Respiration Inhibition[7]	EC_{50}	EC_{15}
	> 1000	>1000
Acute Toxicity		
	$L(E)C_{50}$	NOEC
Daphnia magna (daphnid): 48 hour	>1000	1000
Oncorhynchus mykiss (rainbow trout): 96 hour	>1000	1000
Pseudokirchneriella subcapitata (green alga): 72 hour	>300	300
Chronic Toxicity		
	EC_{50}	NOEC
Ceriodaphnia dubia (daphnid): 7-Day Survival and Reproduction	>9.4	4.8
	LOEC	NOEC
Pimephales promelas (fathead minnow): Early Life Stage (survival and growth)[8]	> 1.0	1.0*
Chironomus riparius (sediment dwelling midge): Full Life Cycle[9]	41	13
N-ACETYLATED DEGRADATION PRODUCT		
Acute Toxicity	$L(E)C_{50}$	NOEC
Daphnia IQ (non-GLP screen)	>600	300

* NOEC used to calculate the PNEC

Document Approval Record

Document Name: EA Pregabalin Spinal Cord 18NOV2011 (Supplement to NDA No. 21-446)

Document Title: Environmental Assessment: Pregabalin for Use in the Management of Central Neuropathic Pain due to Spinal Cord Injury (Supplement to NDA No. 21-446)

Signed By:	Date(GMT)	Signing Capacity
Ericson, Jon F	18-Nov-2011 19:56:47	Final Approval

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/s/

RAANAN A BLOOM
05/16/2012

NAKISSA SADRIEH
05/16/2012

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmaceutical Science/Immediate Office

Memorandum

Date: May 16, 2012

From: Raanan A. Bloom, Ph.D.
OPS/IO/SRS

To: Swati Patwardhan
ONDQA/Div III

Through: Nakissa Sadrieh, Ph.D.
OPS/IO/SRS

Subject: NDA 21-446/S-028 / Lyrica® (pregabalin) Capsules
Environmental Assessment Review

Submission Date: November 18, 2011

Pfizer Inc
235 East 42nd Street
New York, NY 10017

Background

This environmental assessment (EA) dated November 18, 2011, supports new drug application NDA 21-446/S-028 for Lyrica® (pregabalin) Capsules, indicated for the management of central neuropathic pain secondary to spinal cord injury.

Review of the Current Submission

The EA was prepared in accordance with 21 CFR Part 25 by Pfizer Inc. The EA is basically the same EA as was previously submitted and approved for Lyrica® (pregabalin) Capsules (EA date: November 17, 2006; FONSI date: May 14, 2007). In this EA, there is a change in estimated predicted sales of pregabalin and the related expected introductory concentration (EIC) is provided. Additionally, two new chronic toxicity studies have been submitted.

The sponsor estimates the projected market usage of Lyrica® for the first five years (through 2017) to be (b) (4) for all dosage forms and strengths. The incremental usage due to

SCI indication [redacted] For all indications, this is a decrease of [redacted] from the last approval. Using this information and the algorithm described in the FDA EA 'Guidance for Industry' document, the EIC of Lyrica® in the aquatic environment is estimated to be [redacted] based on the projected market usage of [redacted] (2017). Additionally, the projected market usage of [redacted] (2011) submitted with the previous EA on November 17, 2006, was not reached and the applicant has reported a revised market usage of [redacted] retroactive for 2011 (updating the market usage submitted with the previous application dated November 17, 2006), indicating a decrease of [redacted] in market usage between the last EA (November 17, 2006) and the current EA (November 18, 2011).

This estimate assumes that Lyrica® is not metabolized, not subject to environmental depletion mechanisms, or diluted by receiving waters. Therefore, the EIC equals the Maximum Expected Environmental Concentration (MEEC) at the point of introduction into the aquatic environment. It is assumed that product use is evenly distributed throughout the U.S.

Environmental effects data ($L(E)C_{50}$ and NOEC) include acute toxicological studies in *Daphnia magna*, *Oncorhynchus mykiss* and *Pseudokirchneriella subcapitata* and chronic toxicological studies in *Ceriodaphnia dubia, Pimephales promelas and Chironomus riparius*. Microbial inhibition testing was performed and the MIC for all microorganisms and activated sludge tested was >997mg/L.

In addition to the ecotoxicity data submitted with the previous EA on November 17, 2006, the ecotoxicity of pregabalin to 2 aquatic species was investigated for chronic endpoints including an Early Life-Stage toxicity test with fathead minnow (*Pimephales promelas*), following OECD guideline #210 and a Full Life-Cycle toxicity test with Sediment-Dwelling Midges (*Chironomus riparius*) Under Static Conditions, following OECD guideline #218. Studies are summarized in Table 1.

Table 1.

Study Title	Organism	Endpoint	Mean Measured Concentrations	LOEC	NOEC
Full Life-Cycle toxicity (OECD 218)	*Chironomus riparius*	hatching success, survival and growth (length and dry weight)	0.071, 0.14, 0.25, 0.50 and 1.0 mg a.i./L	[redacted]	
Early Life-Stage toxicity (OECD 210)	*Pimephales promelas*	midge emergence	0.14, 0.45, 1.2, 4.0, 13 and 41 mg a.i./kg dry weight		

For both species tested, the No Observable Effect Concentration (NOEC) was at least three orders of magnitude greater than the EIC. Fathead minnow was found to be the most sensitive species and therefore used to evaluate the PEC/PNEC risk assessment for total pregabalin usage. The PEC/PNEC ratio was three orders of magnitude below the threshold value of 1.0 and subsequently, no adverse environmental effect was identified.

Comments and Conclusions

Based on FDA EA guidance and an evaluation of the information provided in this and the previous EA for Lyrica®, no further testing is required and no adverse effects are expected from the introduction of pregabalin into the environment due to the use of Lyrica®.

A Finding of No Significant Impact (FONSI) is recommended.

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/s/

RAANAN A BLOOM
05/16/2012

NAKISSA SADRIEH
05/16/2012