CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

200533Orig1s000

REMS

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Initial Date of Approval: August 25, 2011

NDA 200533

NUCYNTA® ER (tapentadol) tablets

Opioid analgesic

Janssen Pharmaceuticals, Inc.
Titusville, NJ 08560
1-800-526-7736

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOALS

The goals of the NUCYNTA® ER REMS are:

- To inform patients and healthcare professionals about the potential for abuse, misuse, overdose, and addiction to NUCYNTA® ER.
- To inform patients and healthcare professionals about the safe use of NUCYNTA® ER.

II. REMS ELEMENTS

A. Medication Guide

In accordance with 21CFR208.24 a Medication Guide will be dispensed with each NUCYNTA® ER prescription.

This Medication Guide is part of the REMS and is appended.

B. Elements to Assure Safe Use

1. Healthcare professionals who prescribe NUCYNTA® ER will receive training.

a. Janssen Pharmaceuticals, Inc. will ensure that training will be provided to healthcare professionals who prescribe NUCYNTA® ER. To become trained, each prescriber will be provided with the NUCYNTA® ER educational materials. Training will address the following:

i. Proper patient selection;

ii. Appropriate NUCYNTA® ER dosing and administration;

iii. General principles of safe opioid use including information about opioid abuse and how to identify patients who are at risk for addiction;

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iv. Potential abuse, misuse, overdose, and addiction from exposure to opioids, including NUCYNTA® ER;

v. Risks of NUCYNTA® ER including:

1. The risk of overdose caused by exposure to an essentially immediate-release form of tapentadol by consuming split, broken, chewed, crushed, or dissolved NUCYNTA® ER tablets;

2. The risk of overdose in patients who have not developed tolerance to the sedating or respiratory-depressant effects of opioids when using an initial dose of NUCYNTA® ER greater than 50 mg twice daily (total daily dose of 100 mg);

3. The risk of addiction from exposure to NUCYNTA® ER

vi. Information to counsel patients on the need to store opioid analgesics safely out of the reach of children and household acquaintances, and the need to properly dispose of unused drugs when no longer needed by the patient and not to share drugs with anyone for any reason; and

vii. The importance of dispensers providing each patient a Medication Guide with each prescription and instructing the patient to read it.

b. Janssen Pharmaceuticals, Inc. will ensure that within 3 weeks after approval of the NUCYNTA® ER REMS, a Dear Healthcare Professional letter will be mailed to prescribers most experienced in treating chronic pain with opioid agonists, including pain specialists, physiatrists, and primary care physicians. This letter is designed to convey and reinforce the risks of abuse, misuse, overdose, and addiction of NUCYNTA® ER as well as the need to complete the NUCYNTA® ER REMS Education Program. This letter will be available on the Janssen Pharmaceuticals, Inc. website (www.NUCYNTAERREMS.com) for a time period of 1 year from the date of the mailing.

c. The mailings will also include the following NUCYNTA® ER REMS training materials:

i. A copy of the full Prescribing Information (PI)

ii. NUCYNTA® ER Medication Guide

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iii. Prescribing NUCYNTA® ER Healthcare Professional Education Program: A Guide for Healthcare Professionals Who Intend to Prescribe NUCYNTA® ER

iv. NUCYNTA® ER Education Confirmation Form

d. Additional printed training material will be available through field-force distribution and by calling the toll-free number at Janssen Pharmaceuticals, Inc. (1-800-526-7736).

e. The training material will also be available for download at www.NUCYNTAERREMS.com.

f. Janssen Pharmaceuticals, Inc. will maintain a list of all prescribers who have completed the NUCYNTA® ER REMS Education Program.

Prescribers will be re-trained every two years or following substantial changes to the NUCYNTA® ER REMS. Substantial changes may include changes to the NUCYNTA® ER Full Prescribing Information, NUCYNTA® ER Medication Guide, or NUCYNTA® ER REMS that require substantial modification of the educational materials.

The following materials are part of the REMS and are appended:

- Dear Healthcare Professional Letter,
- Prescribing NUCYNTA® ER Healthcare Professional Education Program: A Guide for Healthcare Professionals Who Intend to Prescribe NUCYNTA® ER, NUCYNTA® ER Education Confirmation Form, and
- NUCYNTA® ER REMS website screenshots.

C. Implementation System

Because NUCYNTA® ER can be approved without the Elements to Assure Safe Use described under FDCA 505-1(f)(3)(B), (C), and (D) of the Act, an implementation system is not required.

D. Timetable for Submission of Assessments

Janssen Pharmaceuticals, Inc. will submit REMS Assessments to the FDA every 6 months for the first year from the date of approval of the REMS, and annually thereafter. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment will

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conclude no earlier than 60 days before the submission date for that assessment. Janssen Pharmaceuticals, Inc. will submit each assessment so that it will be received by the FDA on or before the due date.

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