CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-782

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

1.3.5.1 Patent Information

Reference is made to the subject NDA 21-782 for [illegible] (ramelteon) tablets for the treatment of insomnia and the requirements of 505 (b)(1) of the Federal Food, Drug and Cosmetic Act as amended and 21 CFR 314.501(c)(2).

Section 505(b)(1) of the Federal Food, Drug and Cosmetic Act requires that "The applicant shall file with the (new drug) application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug"

The following patents were issued for TAK-375. The drug product name for this chemical entity is [illegible]

21 CFR 314.53 (c) (i), (ii), (iii), (iv)

US Patent No.	**Expiration Date**	**Type of Patent**	**Patent Owner**	**US Representative**
6,034,239	March 7, 2017	Drug substance, Compound	Takeda Pharmaceutical Company, Ltd. (TCI)	Takeda Global Research and Development Center, Inc.

1.3.5.2 Patent Certification

Reference is made to the subject NDA 21-782 for [redacted] (ramelteon) tablets for the treatment of insomnia and the requirements of 505 (b)(1) of the Federal Food, Drug and Cosmetic Act as amended and 21 CFR 314.501(c)(2).

Declaration under 21 CFR 314.53(c)(2)

The applicant declares that Patent No, 6,034,239 covers the drug substance, compound.

This product is the subject of this application for which approval is sought.

As provided for under the Patent Term Restoration Act, Takeda Global Research & Development Center, Inc. will be requesting patent term restoration upon receipt of approval of [redacted] (ramelteon).

Appears This Way
On Original

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