FDA tells drug giant to come clean about Alzheimer's drug

The Food and Drug Administration (FDA) in the U.S. has warned a major drug company about misleading the medical profession over a drug for dementia.

The drug giant Novartis has been given a warning letter about claims they make about the drug Exelon.

The FDA says promotional material about the drug's effectiveness and risks are not justified and they want the company to stop using the material and to circulate new information to correct the misleading statements.

The U.S. health officials say claims appearing on a file card for use by health-care professionals about Exelon capsules and oral solution, suggest the medication Exelon is safer or more effective than has been demonstrated.

The FDA has asked Novartis to stop using the material and to circulate new information correcting the statements.

The FDA also says the promotional material encourages the use of Exelon in circumstances other than those for which the drug has been shown to be safe and effective which is a concern for the public's health.

The FDA letter dated August 8 wants the violations corrected and has urged the company to stop publicising the information 'immediately'.

The agency says presentations of the drug's safety were misleading, as serious risks including gastrointestinal reactions are not mentioned.

Exelon, known generically as rivastigmine, is approved to treat the mild to moderate dementia seen in Alzheimer's disease.

The Novartis file card overstates Exelon's benefits and suggest it can be used with another Alzheimer's drug, Forest Laboratories Inc's Namenda, a combination that is not approved by the FDA.

Novartis also sells an Exelon patch.

Novartis says it is taking the warning seriously and will discuss it with the FDA, and says the information 'will be corrected'.