DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

O. Lucy Castro
Director, Worldwide Regulatory Strategy
Pfizer, Inc.
235 East 42nd Street
New York, New York 10017-5755

Re: NDA #s 20-235, 20-882
Neurontin® (gabapentin)
MACMIS # 10738

Dear Ms. Castro:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has identified a model (#NE 102254) for Neurontin (gabapentin) that is in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations because it makes representations about Neurontin which are false or misleading.

On one side, the model has a presentation of the human brain with full presentation of the hippocampus, the cerebellum, lower medullary structures leading to the spine, and the cerebrum with a prominent mention of the product name below. On the opposite side of the model is a heading "Mechanism of Action," under which are illustrations of cellular activity resulting from the administration of Neurontin and another prominent mention of the product name. The cellular activities within this " Mechanism of Action" include: a decrease in "Action potential frequency," an increase in "GABA synthesis," and increase in "GABA release," and the "Regulat[ion] of intracellular Ca++."

Specifically, DDMAC has the following objections:

The presentation on the model of illustrations of cellular activity resulting from the administration of Neurontin ("Mechanism of Action"), in conjunction with the presentation of the human brain, and the prominent display of the name Neurontin makes representations about how Neurontin acts in the human brain. This presentation along with the depiction of the human brain and the prominent display of the name "Neurontin" suggest that the mechanism of action of Neurontin has been established in the human brain. This suggestion of proof of the mechanism of action is false. Specifically, it is contrary to the language in the approved product labeling that states that "[t]he mechanism by which gabapentin [Neurontin] exerts its anticonvulsant action is unknown."

Furthermore, the full presentation of the aforementioned areas of the human brain accompanied by purported "Mechanism of Action" and the prominent display of the name "Neurontin" is misleading because it suggests that Neurontin is useful for a broader range of CNS conditions than has been

demonstrated by substantial evidence (i.e., it can be used for the treatment of any specific or non-specific brain disorder thought to involve the GABA-ergic neurotransmitter system that can originate in these parts of the brain). Most obviously, the solo and prominent mention of the name Neurontin suggests that Neurontin can be used as monotherapy for various CNS disorders, notwithstanding that with respect to brain disorders, Neurontin is only indicated as "adjunctive therapy in the treatment of partial seizures with or without secondary generalization in patients over 12 years of age with epilepsy" and as "adjunctive therapy in the treatment of partial seizures in pediatric patients age 3-12 years."

To address these objections, DDMAC recommends that Pfizer do the following:

1. Immediately discontinue the use of this model and any other promotional material with the same or similar issues.

2. Respond to this letter within ten days. Your response should include a statement of your intent to comply with the above, a list of all promotional materials with the same or similar issues, and your methods for discontinuing these promotional materials.

If you have any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-42, rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID # 10738 in addition to the NDA number.

Sincerely,

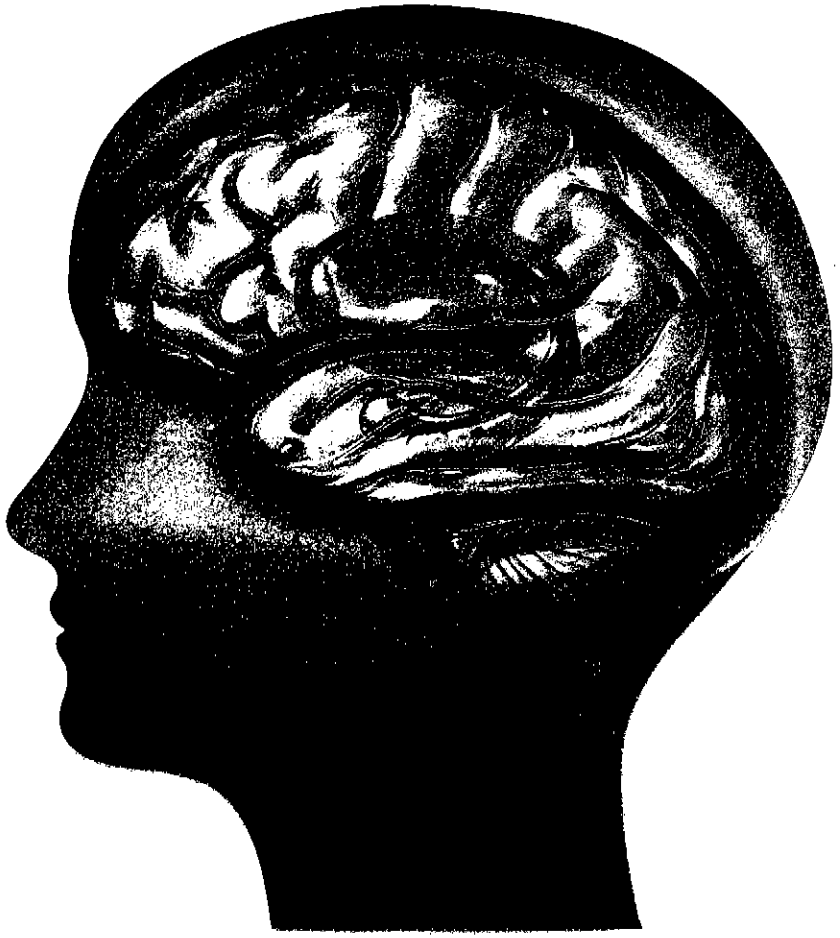
{See appended electronic signature page}

Lisa L. Stockbridge, Ph.D.
Regulatory Reviewer
Division of Drug Marketing,
Advertising and Communications

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

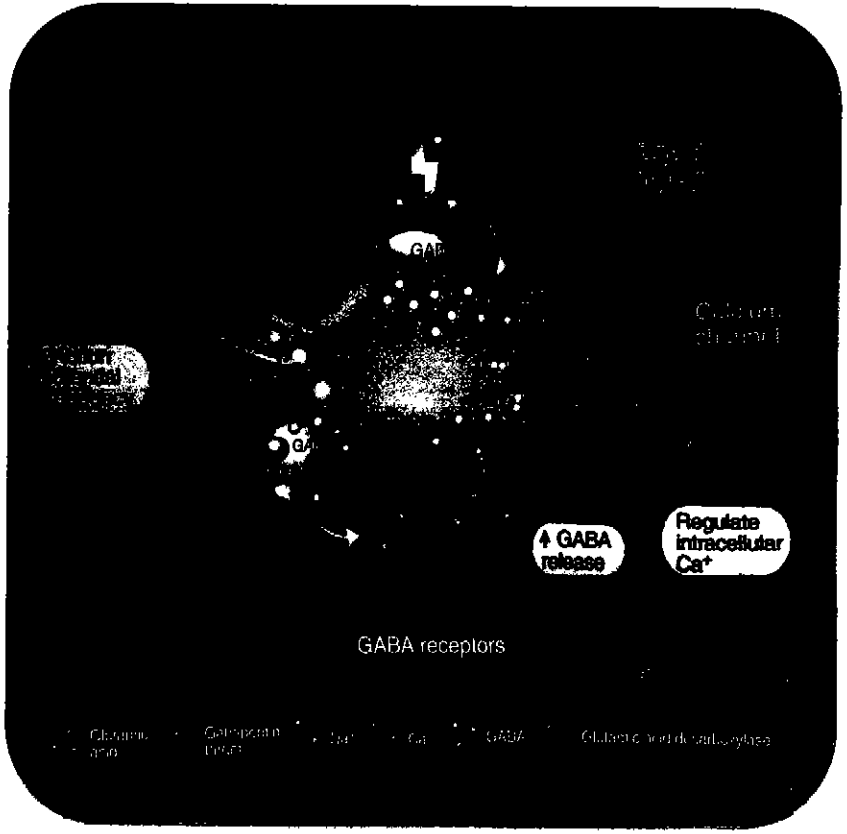
/s/

Lisa Stockbridge
7/1/02 05:00:54 PM



NEURONTIN®
(gabapentin)

MECHANISM OF ACTION



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