

**Exhibit 2**

# **Approval Letter**



MAY 16 1991

Guidelines, Inc.  
Attention: David M. Cohen, Ph.D.  
18441 N.W. 2nd Avenue  
Miami, FL 33169

MAY 16 1991

Docket No. 89P-0399/CP

Dear Sir:

This is in response to your petition filed on September 20, 1989 requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Carbamazepine Suspension 200 mg/5 mL. The listed drug product to which you refer in your petition is Carbamazepine Tablets (Tegretol) 200 mg, manufactured by Geigy Pharmaceuticals.

Reference is also made to your communications dated October 4, 1990 and December 11, 1990.

We have reviewed your petition under Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act (Act), and have determined that it is approved. This letter represents the Agency's determination that an ANDA may be submitted for the above-referenced product.

Your request involves a change in dosage form from that of the listed drug product (i.e., from tablet to suspension). The type of change you request is the type of change authorized under Section 505(j)(2)(C) of the Act.

Under Section 505(j)(2)(C) of the Act the Agency must approve a petition seeking a change in dosage form unless it finds that investigations must be conducted to show the safety and effectiveness of the differing dosage forms.

The Agency has determined that the change in dosage form that you request does not pose questions of safety or effectiveness. The basis for this determination is that the proposed product will have the same use, doses, and route of administration as the listed drug. Therefore, the proposed product can be expected to have the same therapeutic effect as the listed drug.

The approval of this petition to allow an ANDA to be submitted for the above-referenced product does not mean that the Agency has determined that an ANDA will be approved for the product. The determination that an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the Agency.

89P-0399

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

To permit review of your ANDA submission you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved the product will, among other things, be required to meet current bioequivalence requirements under Section (j)(2)(A)(iv) of the Act. To demonstrate bioequivalence, you must conduct a three-way bioequivalence study comparing the proposed product to carbamazepine tablets and the currently marketed oral suspension. We suggest that you contact the Director, Division of Bioequivalence at (301) 295-8290 to determine the specific requirements for this product. Because of the change requested in this petition, labeling for the proposed product will require substantial revision. To decrease the possibility of confusion in the marketplace, the proposed product labeling would need to clearly distinguish the differences from the listed product and the currently marketed oral suspension (i.e., strength, dosage form, and dosing schedule). The Agency will review proposed labeling and description of the dosage form and may request changes to help assure safe use of the proposed product. During the review of your application, the Agency may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you should refer in your ANDA to the petition docket number above, and include a copy of this letter in the ANDA submission.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, HFA-305, Room 4-62, Parklawn Building, 5600 Fishers Lane, Rockville, MD.

Sincerely yours,

Roger L. Williams, M.D.  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research

cc: HFD-84  
HFD-1  
HFD-1 (Chron. File)  
HFD-630  
HFD-650 (Dighe)  
HFD-300  
HFD-360  
HFA-305  
HFA-224  
GCF-1/Adams  
jmk/4-15-91/89P0399.pet (pet)  
F/T/ by GJohnston

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE