Dear Ms. Glamkowski:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

<table>
<thead>
<tr>
<th>Application</th>
<th>Drug Product</th>
<th>Submitted on:</th>
<th>Received on:</th>
<th>Provides for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA 20-505/S-010</td>
<td>Topamax (topiramate) Tablets</td>
<td>December 13, 1999</td>
<td>December 14, 1999</td>
<td></td>
</tr>
<tr>
<td>NDA 20-844/S-006</td>
<td>Topamax (topiramate capsules) Sprinkle Capsules</td>
<td>December 14, 1999</td>
<td>December 15, 1999</td>
<td></td>
</tr>
<tr>
<td>NDA 20-505/S-017</td>
<td>Topamax (topiramate) Tablets</td>
<td>June 28, 2002</td>
<td>July 1, 2002</td>
<td>A change in the recommended daily dose of topiramate and an update to the relevant clinical/safety sections of labeling based on results of the TOPMAT-EPAJ-119 study.</td>
</tr>
<tr>
<td>NDA 20-844/S-014</td>
<td>Topamax (topiramate capsules) Sprinkle Capsules</td>
<td>June 29, 2002</td>
<td>July 1, 2002</td>
<td></td>
</tr>
</tbody>
</table>

We also acknowledge receipt of the following additional submissions to:

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>December 8, 2003</td>
<td>October 15, 2003; November 11, 2003;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>November 14, 2003; December 8, 2003</td>
</tr>
</tbody>
</table>

We have completed our review of these applications, as amended. Accordingly, these applications are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

**Labeling**
The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 20-505 S-010/S-017/S-019 NDA 20-844 S-006/S-014/S-016.” Approval of these submissions by FDA is not required before the labeling is used.

**Promotional Material**
In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

**Dear Healthcare Professional Letter**
As we agreed, you will send a “Dear Health Care Professional” letter informing health care professionals about the labeling changes pertaining to metabolic acidosis. When the letter is issued, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).
If you have any questions, call Jacqueline H. Ware, Pharm.D., Senior Regulatory Project Manager, at (301) 594-2850.

Sincerely,

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/
---------------------
Russell Katz
12/16/03 04:18:53 PM