DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 28 1999

TRANSMITTED VIA FACSIMILE

Nancy Cafmeyer
Vice President of Regulatory Affairs
Jones Pharma Incorporated
1945 Craig Road
P.O. Box 46903
St. Louis, MO 63146

RE: NDA #10-379
Cytomel (liothyronine sodium tablets)
MACMIS ID# 7753

Dear Ms. Cafmeyer:

Reference is made to your February 16, 1999 submission of promotional materials for Cytomel on Form FDA 2253 to the Division of Drug Marketing, Advertising, and Communications (DDMAC). The materials consisted of an accordion folded file card and a portfolio piece. DDMAC, in consultation with the Division of Metabolic and Endocrine Drug Products (DMEDP), has reviewed the materials and determined that they are in violation of the Federal Food, Drug, and Cosmetic Act (ACT) and its implementing regulations. Specifically, DDMAC objects to the pieces for the following reasons:

1. The overall theme of the materials suggest that Cytomel is effective in the treatment of depression. The pictorial representations of a patient exhibiting symptoms of depression on the front cover contrasted with the same patient on the back cover exhibiting no such symptoms, combined with the intervening message of Cytomel's effectiveness, imply that Cytomel is indicated for the relief of the symptoms of depression. However, Cytomel is not approved for the treatment of depression. Moreover, it is our understanding, from information we have reviewed, that the message Jones' representatives are leaving in the marketplace is that Cytomel augments antidepressant therapy.

   In addition, the reference to "early clinical response" implies that Cytomel is useful in patients who are awaiting clinical response to a prescribed antidepressant medication. However, promotion of this combination therapy is not consistent with the approved product labeling (PI). The use of Cytomel with tricyclic antidepressants appears in the Precautions section of the PI because of the risk of cardiac arrhythmias associated with this combination.

The PI does not address the use of Cytomel with selective serotonin reuptake inhibitors (SSRIs) in any manner.

The presentation of the only reference to the approved indication, "when T3 thyroid hormone replacement therapy is required", is not sufficient to overcome the general theme of the remainder of the advertisements.

2. The promotional materials fail to present information relating to side effects and contraindications with a prominence reasonably comparable with the presentation of information relating to the effectiveness of the drug. For example:

   The information in the boxed warning regarding the use of Cytomel in obese patients does not appear anywhere in these materials.

   The single panel of the file card and the half page of the portfolio piece do not adequately present the necessary risk information with a prominence that is reasonably comparable to the prominence of the claims of the product.

Jones Pharma should immediately discontinue the dissemination of these and all other promotional materials that contain the same or similar violations. Your response to this letter should include a list of all similarly violative promotional materials and your proposed method for discontinuing their use. It should be received by this office no later than ten days from the receipt of this letter. It should by directed to 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 #7753 in addition to the NDA number.

Sincerely,

/S/

Margaret M. Kober, R.Ph.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications