



Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

Lynne M. Tracey
Associate Director, Regulatory Affairs
Procter & Gamble Pharmaceuticals, Inc.
Health Care Research Center
8700 Mason-Montgomery Road
P.O. Box 8006
Mason, OH 45040-8006

RE: NDA # 20-835
Actonel (risedronate sodium tablets)
MACMIS # 10400

Dear Ms. Tracey:

This letter refers to your September 28, 2001, submission of television broadcast direct-to-consumer advertisements for Actonel to the Division of Drug Marketing, Advertising, and Communications (DDMAC) under cover of Form FDA 2253. The advertisements included "Book: 60 PGAN 0025" and "Risk: 60 PGAN 0018." DDMAC has reviewed these disseminated advertisements and has determined that they are in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Specifically, we object for the following reasons:

Minimization of the Role of the Healthcare Provider in the Prescribing Process

These advertisements are misleading because they fail to make any reference to the need to consult a healthcare provider. This presentation undermines the role of the healthcare provider in determining whether Actonel is an appropriate choice for the patient. This lack of disclosure, in combination with the overall tone of the advertisements, minimizes the prescription-only status of Actonel by misleadingly implying that the consumer can judge her own degree of risk for osteoporosis and choose her own therapy accordingly. This misleading impression is not remedied by the single reference that Actonel is a prescription drug.

Failure to Fulfill Adequate Provision Requirements

The advertisements do not fulfill the requirement for ensuring adequate provision for the dissemination of the approved product labeling information because they do not address the information-seeking needs of consumers who only want to receive their prescription drug information from a healthcare provider.

Inadequate Communication of Risk Information

The advertisements fail to adequately communicate risk information about Actonel because the risk information is presented in the audio portion of the advertisement concomitant with a visual presentation of fast-paced, rapidly-changing, distracting images. This presentation interferes with the viewer's ability to comprehend and process the audio presentation of Actonel's important risks.

Inadequate Communication of Contextual Information

The advertisement "Book: 60 PGAN 0025" fails to adequately communicate important contextual information regarding the risk factors for the development of osteoporosis. This important information regarding the appropriate population for Actonel therapy is presented on the same screen as the Actonel logo, the toll-free telephone number, and the prescription-only superimposition. The information does not appear on the screen long enough for the viewer to read, comprehend, and process each of these components.

Requested Actions

We request that these broadcasts, and all other promotional materials with the same or similar violative presentations, be immediately discontinued. We request that you submit a written response to this letter no later than October 23, 2001, including your plan to comply with our request. Your written response should include a list of all materials that you have discontinued and the date that they were discontinued.

Please direct your response to me 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 #10400 in addition to the NDA number.

Sincerely,

{See appended electronic signature page}

Margaret M. Kober, R.Ph.
Regulatory Review Officer
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/

Margaret Kober
10/9/01 12:56:09 PM