



TRANSMITTED BY FACSIMILE

Jan L. English
Associate Director
Global Regulatory Affairs
Promotion & Labeling
Pharmacia Corporation
7000 Portage Road
Kalamazoo, MI 49001

RE: NDA# 20-280
Genotropin (somatropin [rDNA] origin for injection)
MACMIS ID# 10441

Dear Ms. English:

This letter responds to your October 18, 2001, letter to the Division of Drug Marketing, Advertising, and Communications' (DDMAC) regarding the telephone conversations between DDMAC and Pharmacia Corporation (Pharmacia) on September 26 and October 15, 2001. The subject of the telephone conversations was the promotion of Genotropin for the long-term treatment of growth failure in children born small for gestational age (SGA) who fail to manifest catch-up growth by age 2 and Pharmacia's dissemination of material identified as UD0016412.

DDMAC reviewed this disseminated material and determined that it is in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations because it constitutes a product-specific promotional labeling piece but does not satisfy the regulatory requirements for such materials. The piece states "In the United States, there has been no approved option for treating growth failure in children born SGA who fail to manifest catch-up growth. Until now. These children may benefit from the first and only approved treatment for growth failure in children born SGA who don't catch up." These statements render this piece to be product-specific for Pharmacia's Genotropin. Therefore, we object to the following:

Inadequate Communication of Approved Indication

The claim "the first and only approved treatment for growth failure in children born SGA who don't catch up" is misleading because it fails to provide adequate information regarding the full approved SGA indication, including limitations. Genotropin is only approved for the long-term treatment of growth failure in children born small for gestational age (SGA) who fail to manifest catch-up growth **by age 2.** (Emphasis added)

Furthermore, the material presents the terms "light for dates, intrauterine growth retardation, small for dates, and dysmature" in a manner that misleadingly suggests that they are interchangeable with the term "small for gestational age." This presentation misleadingly implies that Genotropin is useful in a broader range of conditions than has been demonstrated by substantial evidence.

Lack Of Fair Balance

Promotional materials must present information regarding the risks associated with the use of a drug in a manner that is reasonably comparable to the presentation of claims regarding the drug's efficacy. This promotional piece, however, fails to convey any information about the contraindications, warnings, precautions, or adverse reactions associated with Genotropin.

DDMAC has reviewed your response to our telephone conversations and notes the statement that this material was used in a one-time mailing and has been discontinued. You also indicated that no similar materials are in use.

In light of these representations, we consider this matter closed. We will, however, continue to closely monitor promotional materials for Genotropin and will consider alternative corrective measures if further violative dissemination occurs.

If you have any questions or comments, please contact 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 # 10441 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
12/13/01 12:39:56 PM

er dates

in for dates

FOR THE YEAR

light for

INTRAUTERINE GROWTH

Small

dysmature

Small for

WORLD

So, what is

So, what is SGA?

SGA is a leading provider of...
...the most...
...years of...
...the most...
...years of...
...the most...
...years of...

Utilization

Utilization of...
...the most...
...years of...
...the most...
...years of...
...the most...
...years of...

Our science is growing™

SGA is a leading provider of...
...the most...
...years of...
...the most...
...years of...
...the most...
...years of...

