DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTAL VIA FACSIMILE

SEP 17 1998

Marie De Gayner Kuker
Director of Regulatory Affairs
Orphan Medical, Inc.
13911 Ridgedale Drive
Suite 475
Minnetonka, Minnesota 55305

Re: Orphan Medical Website
MACMIS ID #6918

Dear Ms. De Gayner Kuker:

As part of its routine monitoring, the Division of Drug Marketing, Advertising, and Communications (DDMAC) became aware of a World Wide Web (web) site for Orphan Medical, Inc. (Orphan Medical). Orphan Medical's web site contains a web page titled "Orphan Medical Product Information." DDMAC reviewed this web page and determined it: 1) promotes Orphan Medical's approved products without fair balance; and, 2) promotes products prior to their approval in violation of 21 CFR 312.[1]

The "Orphan Medical Product Information" web page is a list of approved and investigational products and the products' "applications." For each approved product, the "application" is the approved indication. Each approved product name is also a hypertext link to the full prescribing information and sometimes additional product information. The web page contains no risk information about the approved drugs.

Pre-approval Promotion

The "Orphan Medical Product Information" web page does not distinguish between approved and investigational drugs. The web page presents the investigational drugs and "applications" (indications) in the same list and format as the approved drugs and "applications," except without hypertext links to full prescribing and other information. Under 21 CFR 312.7, however, "A sponsor or investigator . . . shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation . . . . " Presenting the investigational drugs and indications in the same list and format as the

[1] Http://www.orphan.com/product_information.dbm as of 9/17/98.

approved drugs and indications suggests that the investigational drugs have been cleared for marketing when such a determination has not been made.

Fair Balance

Under section 502(a) of the Act, "a drug . . . shall be deemed to be misbranded . . . if its labeling is false or misleading in any particular." In determining whether labeling or advertising is misleading, DDMAC evaluates whether risk information is presented in a manner that is reasonably comparable to efficacy information. The "Orphan Medical Product Information" web page contains no risk information, nor references to risk information, to balance the efficacy information. Although risk information is contained in the full prescribing information, the link to the full prescribing information alone is insufficient to meet the requirements that labeling not be misleading or that advertisements contain fair balance.

Action

To address these violations, Orphan Medical products should either remove the cited web page from the web or change it as follows:

1) The information on investigational drugs should clearly identify the drugs as investigational, should not make claims of safety or effectiveness, and should not be promotional in tone; and,

2) The information on approved drugs should balance the effectiveness claims with risk information.

Orphan Medical should also modify any other promotional materials that may contain the same violations as the web site.

Orphan Medical should respond by October 1, 1998, about how it will comply with DDMAC's request. The response, or any questions or comments, may be faxed to me at 301-594-6759 or sent by mail to the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857. Only written communications are official.

In future correspondence regarding this matter, please refer to MACMIS ID # 6918.

Sincerely,

Melissa M. Moncavage
Division of Drug Marketing,
Advertising, and Communications