



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 2 1997

TRANSMITTED VIA FACSIMILE

Diane Scudiery
AlfaCell Corporation
225 Belleville Avenue
Bloomfield, NJ 07003

RE:

Onconase
MACMIS ID #5454

Dear Ms. Scudiery:

As part of our routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has determined that AlfaCell Corporation (AlfaCell) is promoting an unapproved product, in violation of the Federal Food, Drug and Cosmetic Act (Act) and regulations promulgated thereunder. Specifically we refer to promotional activities in AlfaCell's commercial exhibit booth at a recent medical convention. AlfaCell distributed copies of a bibliography of abstracts and publications regarding an investigational agent, Onconase, and a product fact sheet describing characteristics of Onconase. These activities constitute promotion of an unapproved drug, and are in violation of the Act.

AlfaCell should immediately cease this and all similar activities that promote unapproved drugs. AlfaCell should submit in writing its intent to comply with the above. AlfaCell's written response should be received by DDMAC no later than June 13, 1997, and should be addressed to the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, 5600 Fishers Lane, HFD-40, Rockville, Maryland 20857. DDMAC reminds AlfaCell that only written communication is considered official. In all future correspondence regarding this particular matter, please refer to MACMIS ID #5454 in addition to the IND/NDA number.

Sincerely,

Tracy Acker, Ph.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications