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INTRODUCTION: The sponsor has submitted a BLA supplement supporting a change in the dosing regimen for treatment of Hepatitis C. This report summarizes the adverse event information on Roferon-A from the FDA database.

METHODS: The spontaneous reporting system (SRS) maintained by the FDA is a passive reporting system with the well-known problems of under reporting and incomplete information. All reported events are coded with up to 4 terms from a standardized dictionary(COSTART).

RESULTS: Search of the SRS found that 1452 domestic and foreign reports of possible adverse events associated with Roferon-A have been received since the 3d quarter of 1986. Of these 66% were submitted via the manufacturer. An additional 25% are from a special study(NDA). The rest are from physicians, pharmacists and the literature. The male:female ratio is 8:5.

The 10 most frequent COSTARTS are:

COSTART	# of reports
Fever	136
Leukopenia	85
Thrombocytopenia	83
Asthenia	77
Dyspnea	70
Flu-like syndrome	63
Rash	62
Pneumonia	51
Sepsis	51
Confusion	48

Other:

Alopecia	36
Abnormal liver test	32
Depression	29
Suicide attempt	25
Urticaria	24
Vasculitis	22
Heart arrest	20
Chest pain	19
Pancreatitis	16
Anti nuclear AB	13

CONCLUSION:

Three reports are the subject of an article on "Vitiligoid lesions in metastatic melanoma treated with alpha interferon" by Oluvaud *et al.* Annals of Dermatology and Venerology, 123:149(1996).

R. Kapit, MD of this office reviewed recently the adequacy of the PI warning on depression and suicide with interferon alfa. Dr. Kapit found the warning to be adequate.

The sponsor has a Revised Package Insert Supplement pending. The proposal is to warn about possible neuropsychiatric deficits and multiple organ failure associated with benzyl alcohol in neonates and infants. A warning about the possible toxicity of benzyl alcohol if there is placental transfer is to be added to the Usage in Pregnancy se 1.

A paragraph on autoimmune antibodies is to be added to the Precautions section.

A warning on Overdosage is also to be added.