Dear Mr. Jones:

Please refer to your supplemental new drug application dated April 16, 2001, received April 17, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Leukeran (chlorambucil) Tablets.

This "Changes Being Effected" supplemental new drug application provides for the following changes:

- Add “myoclonia” to the CNS subsection of ADVERSE REACTIONS.
- Add “Allergic reactions such as urticaria and angioneurotic edema have been reported following initial or subsequent dosing” to the Dermatologic subsection of ADVERSE REACTIONS.
- Revise Reference 46 of the REFERENCE section to provide the most current guidance for the safe handling of anti-cancer agents.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted April 16, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

However, it is the policy of the Office of Drug Evaluation I and the Division of Oncology Drug Products to include only those references which pertain to the handling of antineoplastic agents, listed below. Please update the references at the next printing or within 6 months, whichever comes first.

REFERENCES:


If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD  20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21CFR 314.80 and 314.81.
If you have any questions, call Maureen Pelosi, Project Manager, at (301) 594-5778.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Richard Pazdur
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