DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

ANDA 075547/S-006

PRIOR APPROVAL SUPPLEMENT APPROVAL

West-Ward Pharmaceutical Corp.
U.S. Agent for Eurohealth International Sarl
2 Esterbrook Lane
Cherry Hill, NJ 08003-4099
Attention: J. Barton Kalis
Director, Regulatory Affairs

Dear Sir:

Please refer to your supplemental Abbreviated New Drug Application (sANDA) dated February 9, 2015, received February 9, 2015, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your Abbreviated New Drug Application (ANDA) for Thiotepa for Injection USP, 15 mg/vial.

We acknowledge receipt of your amendments dated April 8, and June 22, 2015.

The supplemental ANDA, submitted as "Prior Approval Supplement," provides for:

> Transfer of the site of drug product manufacture as well as (b) (4) final product release and stability testing to Thymoorgen International GmbH, a wholly-owned subsidiary of Hikma.

We have completed our review of this sANDA, as amended, and it is **approved**.

We remind you that you must comply with the requirements for the approved ANDA described in 21 CFR 314.80-81.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your sANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce

or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

The material submitted is being retained in our files.

Sincerely yours,

William P. Rickman -S

Digitally signed by William P. Rickman -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300043242, cn=William P. Rickman -S
Date: 2015.07.08 13:36:20 -04'00'

For Carol A. Holquist, RPh
Acting Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research