UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Jan 30, 1989

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Information request regarding registration of Gibberellic Acid (GA3) and the Gibberellin GA4/GA7 products of Abbott Laboratories, North Chicago, IL

TO: Mr. Robert Taylor, PM-25
Registration Division (TS-767C)

FROM: Karen L. Hamernik, Ph.D. K. Hamernik 1/30/89
Toxicology Branch (IRS)
Hazard Evaluation Division (TS-769C)

THRU: Marion Copley, DVM, Section Head MCopley 1/30/89
Toxicology Branch (IRS)
Hazard Evaluation Division (TS-769C)

Tox. Chem. File #467

I attended a meeting with Abbott Laboratories, North Chicago, IL on Jan 24, 1989 concerning Abbott's gibberellin products. Several issues arose at that meeting which need to be resolved:

1. Abbott indicated that acute oral and acute dermal studies had been submitted to the Agency for Gibberellic acid (GA3), that these studies had been evaluated and were found to be acceptable support for data requirement fulfillment. I cannot readily determine from Toxicology Branch files which studies Abbott is referring to. These studies do not appear on the current Toxicology Branch one-liner. I need to have the identities of these studies, any reviews of the data you might have in your files, and hardcopies of the original study reports.

2. Abbott was apparently not informed by the Agency about the results of Toxicology Branch reviews of several studies performed with GA3. The titles and Toxicology Branch reviews of these studies (one teratology and three mutagenicity studies) are attached to this memo for your convenience. Please officially inform the company of the results of the Toxicology Branch evaluations of these studies and that some deficiencies exist in these data.

3. I need Confidential Statements of Formulation for all Abbott gibberellin products including Promolin, Provide, and Progib.