October 10, 1977

Mr. John A. Shaughnessy
Products Control Branch (WH-567)
Registration Division
Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460

Dear Mr. Shaughnessy:

On June 2, 1977 you wrote to us regarding our request for the exemption of 2-amino-4, 5-dihydro-6-methyl-4-propyl-5 triazolo-(1, 5-a) pyrimidin-5-one from the requirement of a tolerance. In this letter you advised that it would be necessary for this chemical to be approved as a New Drug.

As you advised, we contacted the Food and Drug Administration. Attached is a copy of the letter they sent to us as a result of their review. Please note they have concluded the chemical is not subject to the drug provisions of the Food, Drug and Cosmetic Act.

In view of this, we request that you proceed with our April 1, 1977 request that this chemical be exempted from the requirement of a tolerance. We feel your prompt attention to this will be to the benefit of all.

Very truly yours,

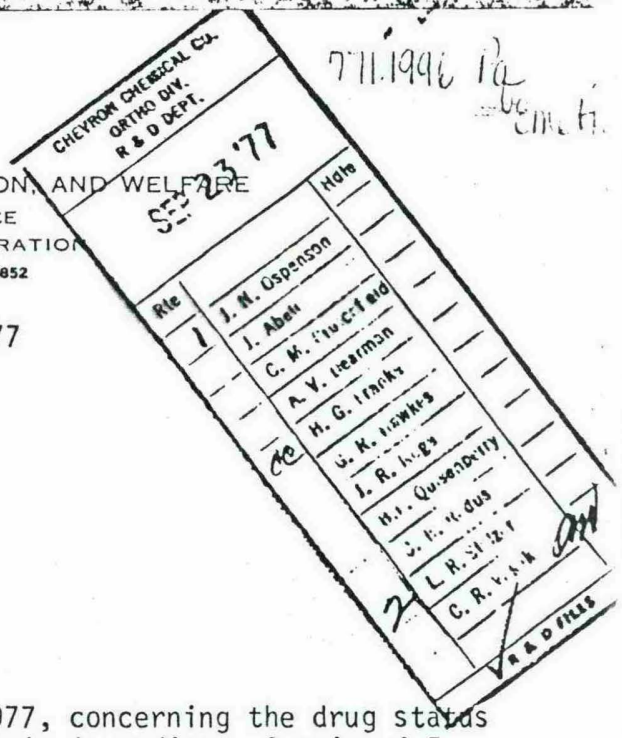
L. R. Stelzer, Manager
Registration & Regulatory Affairs

DFD:df

bcc: C. H. Condron
F. X. Kamienski
J. N. Ospenson
B. F. Quisenberry
E. L. Stripling
C. R. Tanner
J. P. Toffaleti

CUSA-00044451

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852



September 19, 1977

Dr. J. Nils Ospenson, Manager
Research and Development
Chevron Chemical Company
940 Hensley Street
Richmond, California 94804

Dear Dr. Ospenson:

This responds to your letter of June 10, 1977, concerning the drug status of a proposed product which includes an emetic ingredient, 2-amino-4,5-dihydro-6-methyl-4-propyl-s-triazolo(1,5-a)-pyrimidin-5-one (also known as PP-796), in a pesticide formulation, a paraquat dichloride herbicide. We understand that the purpose of the emetic, as a pesticidally inert ingredient, is to induce vomiting in cases of oral ingestion, either accidental or intentional. You state that the Environmental Protection Agency (EPA) wants our opinion as to the drug status and whether or not an approved New Drug Application is required in addition to EPA pesticide requirements.

We conclude that the proposed product would not be subject to the drug provisions of the Federal Food, Drug, and Cosmetic Act. As you indicated in your letter of June 10, and subsequently in a June 15, 1977, meeting with Mr. Heller and Mr. Eshelman of the OTC Compliance Branch, the intended use of the product, as labeled, is strictly as a pesticide. You indicate that the rationale for including the emetic ingredient in the product is to reduce the hazard involved with oral ingestion, either accidental or intentional, of the product. You further indicated that although paraquat dichloride is highly toxic, adverse effects are slow in appearing, thereby possibly resulting in a delay in seeking proper medical treatment. Thus, the inclusion of an effective emetic to automatically induce vomiting may reduce the hazard associated with ingestion of the paraquat dichloride pesticide by promptly starting appropriate medical treatment.

We understand that your firm does not intend to promote the emetic properties of the pesticidally inert ingredient. It is also our understanding that under EPA regulation 40 CFR 180.1001(d), an exemption granted for a particular inert ingredient is for a specific product formulation of a specific firm, and would not be a "blanket" exemption for use of the emetic ingredient in other preparations.

On the basis of the above information, and especially in view of the fact that your firm does not intend, in any manner, to promote the emetic properties of the proposed product, we conclude that the product would not be subject to the drug provisions of the Act.

Although we have concluded that your product is not subject to our jurisdiction, an FDA evaluation of the safety and effectiveness of the emetic ingredient may be necessary in order for the Environmental Protection Agency to adequately consider the petition for exemption of the emetic ingredient as an inert ingredient. Among other considerations, we feel your firm must assure itself that the emetic ingredient would not create added toxicity if the product is retained by the person ingesting it, e.g., ingestion of the paraquat/emetic combination at a level just below the effective emetic dose. We are, therefore, unless otherwise advised by you, retaining the two volumes of summary data you submitted at the June 15, meeting in case EPA requires our evaluation.

We are notifying EPA of our conclusions by forwarding a copy of this letter.

We hope this adequately responds to your inquiry.

Sincerely yours,

Rudolf Apodaca, Director
Division of Drug Labeling Compliance
Bureau of Drugs

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