The Office of the Commissioner
Department of Health & Human Services
Food and Drug Administration

And to:

Daniel J. Simonsen
Compliance Officer
U.S. Food and Drug Administration
One World Trade Center, Suite 300
Long Beach, CA 90802

And To:

Tina R. Smith, M.S.
Captain, U.S. Public Health Service
Director, Office of Unapproved Drugs and Labelling Compliance
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Dear Recipients,

I am writing on behalf of Cholrem Pty Ltd regarding the recent actions taken by the U.S. Food and Drug Administration (FDA) in relation to our Company's product, **REMCHOL**.

I am simply amazed that your Administration could be so wrong as to assert that our product as an "unapproved drug" under the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 USC 355(a).

Misinterpretation of Approval Status

The Company's preliminary research of your own database proves conclusively that the ingredient in our product, **Hydroxypropyl Betadex**, has been approved by your Administration on no fewer than seven separate occasions in the past. This indicates that our product should not be classified as an unapproved drug, as your recent correspondence suggests.

The Company intends to provide a more comprehensive explanation of the misinterpretation in the coming days, but for now your conduct in issuing the following items and disrupting our product shipments is not supported by fact and threatens the health and wellbeing of countless Americans:

1. a "Warning Notice" (Reference 684036) on July 7, 2024;
2. a "Response Letter" on September 12, 2024;
3. "Refusal and Administrative Destruction" notices, such as Notice number 1 on September 26, 2024;

Some of our customers are beyond conventional medical help and rely upon our product for their very existence!

Remchol Cavadex is not an “unapproved drug,” as you assert. It is an innovative therapy that clearly reverses heart disease, the number one killer worldwide and an incurable disease for those who suffer with it. Until the introduction four years ago of Remchol Cavadex, heart disease due to intractable, progressive atherosclerosis was considered essentially terminal.

The Company has been trading with individuals, worldwide and in the USA, for in excess of four years providing Remchol products without so much as a hint of administrative compliance issues.

Yet you decide to deny your citizens this life saving treatment which is not only approved by your organisation but is backed by rigorous science. In supplying tens of thousands of boxes of Remchol the Company has never received a single report of side effects related to Cavadex.

The company only sells its product online through its website which displays all the science of Cavadex on the front page. Consumers read all data before making an informed decision to purchase.

On the company’s website it is declared, in bold font, that Cavadex is NOT FDA APPROVED to treat heart disease.

The Company’s Requirements

The Company demands you to forthwith cease this improper criticism of our product immediately, and advise of the names and addresses of those good people whose products you have chosen to destroy and thereby prevent from receiving our lifesaving technology.

The Company will replace their wrongly-confiscated products immediately. We have consistently provided **REMCHOL** at no cost to U.S. Armed Forces veterans and others in need. The Company is fully committed to ensuring access to its product for the well-being of those who might otherwise die from heart disease.

If you do choose only an enforcement path, rather than a synergistic one with our company, the blood of countless American citizens will be on your hands.

We await your response and a resolution to this matter at your earliest convenience.

Yours sincerely,
Kyle Hodgetts
CEO
Cholrem Pty Ltd