

November 5, 2002

Dockets Management Branch
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Citizen Petition

Dear Sir or Madam:

The undersigned submits this petition, in quadruplicate, in accordance with 21 CFR 10.30 to request that the Commissioner of Food and Drugs to assign a reference listed drug (RLD) status to currently marketed an approved drug product for Cyproheptadine Hydrochloride Tablets 4 mg

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration assign reference listed drug (RLD) product status to currently marketed, approved product listed in the "Approved Drug Products with Therapeutic Equivalence Evaluation (Orange Book).

B. Statement of Grounds

The petitioner is confirmed that current reference listed drug product (RLD) for the Cyproheptadine HCl Tablets 4 mg is "Periactin®" (Merck's product) in Approved Drug Products with Therapeutic Equivalence Evaluation, ("Orange Book") 22nd Edition is no longer available in the market. Please find enclosed letter from the Merck & Co., Inc. that they deleted this product.

C. Environmental Impact

Categorical exclusion is claimed under 21 CFR 25.31.

02P-0479

D. Economic Impact

CP1

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis if requested by the agency.

Dockets Management Branch
Food and Drug Administration
November 5, 2002
Page 2 of 2

E. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

A handwritten signature in black ink, appearing to read "Mukteeshwar Gande", with a horizontal line underneath.

Mukteeshwar Gande, M.S., R.Ph.
Vice President, Scientific Affairs
Corepharma LLC
Telephone (732) 868 1090

Cc: Gary Buehler
Director, Office of Generic Drugs (HFD-600)

October 30, 2002



Mukti Gande, R.Ph.
CoraPharma
215 Wood Avenue
Pharmacy Department
Middlesex, NJ 08846

Dear Ms. Gande:

Thank you for contacting Merck & Co., Inc. regarding the deletion of PERIACTIN® (Cyproheptadine HCl), 4MG TABLETS 100 1/PKG, PSF 32766800. We regret any inconvenience that you may be experiencing as a result of the deletion of our product, and want to assure you that Merck makes every effort to be mindful of the impact our business has on patients and physicians.

We regret that there is no stock available of PERIACTIN® (Cyproheptadine HCl), 4MG TABLETS 100 1/PKG, PSF 32766800, for emergency distribution. Effective immediately, we are unable to accept any orders for PERIACTIN®. In addition, all backorders for PERIACTIN® are canceled.

Merck remains committed to the research and development of innovative products and appreciates your feedback as we strive to continually work toward improving our products and services to our customers.

Thank you again for contacting us.

Sincerely,

A handwritten signature in black ink that reads "George J. DeCecco".

George J. DeCecco, R.Ph.
National Service Specialist

Your Case Number: 2536567