

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852.

2003 10 12 24 2458

[Docket No. 2003D-0478]
Draft Guidance on Marketed Unapproved Drugs; Compliance Policy
Guide; Availability
AGENCY Food and Drug Administration, HHS.
ACTION Notice.

To Whom This May Concern,
Response to: 2003D-0478; Draft Guidance on Marketed Unapproved Drugs Compliance Policy Guide;
Availability 10/20/03 12/22/03

I protest the FDA's enforcement of very old legislation that fails to protect the public's access to drugs that have been on the market longer than the FDA has been in existence. This is especially true concerning single ingredient, sustained-release guaifenesin. This drug is a mainstay in medical treatment, and has been so for hundreds of years. There are no reports of any safety problems of any kind. It is used in the treatment of acute respiratory disease, bronchitis, cystic fibrosis, asthma, infertility and A.I.D.S. It has also found successful, off-label use, in recent years, in the treatment of Fibromyalgia.

By approving Mucinex as the ONLY FDA approved, sustained-release guaifenesin, FDA seriously harmed the health of many thousands of patients using it to successfully treat Fibromyalgia. These patients require a pure, powder based, long-acting, guaifenesin tablet. Many patients require a dose that is less than 600 mg, or more than 600 mg but less than 1200 mg. They can not use Mucinex, as it can not be broken without loss of dose, and destruction of sustained-release properties.

I believe all action against the single ingredient, sustained-release guaifenesin industry needs to be reversed. At the very least (and only if the first option is demonstrably not viable) a time extension should be granted, sufficient to allow for the entire manufacturing industry to provide the FDA with documentation of bio-availability and bio-equivalence of their sustained-release guaifenesin product, with a full return to production and sale in the interim. Pediatric Humibid, in prescription form, should immediately be returned to the public due to the seriousness of the illnesses it treats.

I do not want Mucinex as my only choice of extended release guaifenesin. I want the pure sustained release guaifenesin that I used before the FDA shut this industry.

Yours sincerely,



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2003D-0478

C58