



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Atlanta District Office  
60 8th Street, N.E.  
Atlanta, Georgia 30309

February 5, 2010

**VIA FEDERAL EXPRESS**

**WARNING LETTER  
(10-ATL-08)**

David M. Preston, Chief Executive Officer  
Deston Therapeutics, LLC.  
6320 Quadrangle Dr. Ste 100  
Chapel Hill, NC 27517

Dear Mr. Preston:

On (b)(4) 2009, FDA issued a warning letter to (b)(4) copy attached). As explained more fully in that warning letter, certain drug products that (b)(4) has manufactured are new drugs that lack approved applications as required under the Federal Food, Drug, and Cosmetic Act (the Act). Based on information obtained during FDA's inspection of (b)(4) your firm contracted or otherwise arranged with (b)(4) to manufacture one or more drug products that your firm distributes. These drug products include, but are not necessarily limited to:

- Novahistine DH CIII Liquid (Dihydrocodeine Bitartrate 6.5 mg; Chlorpheniramine Maleate 2 mg; Phenylephrine HCl 4 mg)
- Aquatab C Tablets (Guaifenesin 400 mg; Carbetapentane Citrate 30 mg; Phenylephrine HCl 10 mg)

The above products are drugs within the meaning of section 201(g) of the Act, [21 U.S.C. § 321(g)] because, as demonstrated by their labeling, they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases. Further, they are "new drugs" within the meaning of section 201(p) of the Act [21 U.S.C. § 321 (p)] because they are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. Under sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(a), (d) and 355(a)], a new drug may not be introduced into or delivered for introduction into interstate commerce unless an application approved by FDA under either section 505(b) or (j) of the Act [21 U.S.C. § 355(b) or (j)] is in effect for the drug. Based on our information, there are no FDA-approved applications on file for these drug products.

Additionally, because the above prescription drug products are intended for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written for them so that a layman can use these products safely for their intended

uses, as described in 21 C.F.R. § 201.5. Consequently, their labeling fails to bear adequate directions for their intended uses, causing them to be misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)]. Because the products lack required approved applications, they are not exempt under 21 C.F.R. § 201.115 from the requirements of section 502(f)(1) of the Act. The introduction or delivery for introduction into interstate commerce of these products without approved new drug applications violates section 301(a) and (d) of the Act [21 U.S.C. §§ 331(a) and (d)].

Further, as explained in the warning letter dated **(b)(4)** 2009 to **(b)(4)** the above drug products are adulterated, 21 U.S.C. 351 (a)(2)(B), and thus your firm may not introduce or deliver them for introduction into interstate commerce, 21 U.S.C. § 331 (a).

The violations cited in this letter are not intended to be an all-inclusive statement of violations that may exist in connection with your products. In particular, violations cited in this letter are not necessarily limited to drug products manufactured by **(b)(4)** and may apply to all drug products that you market without FDA-approved applications. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure, and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. If you no longer market the above products, your response should so indicate, including the reasons that, and the date on which, you ceased production.

Your reply should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely,

/S/

LaTonya M. Mitchell, Acting Director  
Atlanta District