



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

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Gary Yingling, Esquire  
1800 Massachusetts Avenue, N.W.  
Kirkpatrick & Lockhart, L.L.P.  
Second Floor  
Washington, D.C. 20036-1221

Re: Docket No. 80N-0146/CP4

Dear Mr. Yingling:

This is in reference to your citizen petition (CP4) dated April 2, 2001, filed under Docket No. 80N-0146 in Dockets Management Branch. The petition requests, among other things, that the Agency revoke the final rule on over-the-counter (OTC) nailbiting and thumbsucking deterrent drug products (21 CFR § 310.536). In addition, the petition also requests that the Agency establish a monograph for nailbiting and thumbsucking deterrent drug products containing cayenne pepper or denatonium benzoate.

The procedures governing the review of citizen petitions are set out in regulations found at 21 CFR 10.30. The regulations provide, among other things, that the Commissioner shall furnish a response to a petition within 180 days of the petition, agency resources and priorities permitting. See 21 CFR 10.30(e). This is to advise you, pursuant to 21 CFR 10.30(e)(2), that because of the existence of other priorities, the Agency is unable to provide a response to the petition at this time.

If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit all inquiries to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852.

Sincerely yours,

Janet Woodcock, M.D.  
Director  
Center for Drug Evaluation and Research

80N-0146

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