



AUG 26 2002

7724 17 20 11 04

Kevin I. Ajoku  
Market Segment Manager  
Bayer Corporation  
100 Bayer Corporation  
Pittsburgh, PA 15205

Re: Docket No. 75N-183H/CP11

Dear Mr. Ajoku.:

This is in reference to your citizen petition (CP11) dated December 28, 2001, filed under Docket No. 75N-183H in the Dockets Management Branch. The petition requests that the agency amend the Tentative Final Monograph for OTC Healthcare Antiseptic Drug Products published June 17, 1994 (59 FR 31402) to include: (1) The additional product categories of food handler handwash, consumer handwash, and consumer bodywash, and (2) up to 1.5 percent triclocarban as a generally recognized safe and effective antiseptic active ingredient for use in OTC healthcare personnel handwashes, foodhandler handwashes, consumer handwashes, and consumer bodywashes.

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

75N-183H

LET 31

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 9.18.02

FROM: Director  
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 75N-183H

TO: Dockets Management Branch, HFA-305

The attached material should be placed on public display under the above referenced Docket No.

This material should be cross-referenced to Comment No. CP11

  
Charles J. Ganley, M.D.

Attachment