



Food and Drug Administration
Rockville MD 20857

JAN 22 2001

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Perry M. Gottesfeld, M.P.H.
Executive Director
Occupational Knowledge International
1255 Post Street, Suite 437
San Francisco, California 94109

Re: Docket No. 00P-1210
Comments No. CPI, C1, and C2

Dear Mr. Gottesfeld:

This letter is sent in reference to a citizen petition (CPI) submitted by Occupational Knowledge International dated March 6, 2000, filed on March 22, 2000 under Docket No. 00P-1210 in FDA's Dockets Management Branch, and amended on June 6, 2000 and July 26, 2000. This petition requested the agency to initiate a formal review of the use, sale, and distribution of coal tar shampoo, soap, and ointment, restrict the sale of products containing coal tar now available over-the-counter to prescription only, and require additional warning language to protect the public health.

The procedures governing the review of citizen petitions are found in FDA's regulations at 21 CFR §10.30. The regulations provide, among other things, that the Commissioner will furnish a response to a petition within 180 days of receipt of the petition, agency resources and priorities permitting. See 21 CFR §10.30(e).

The agency has completed its review of the material submitted in support of this petition and the comments submitted to the public docket. The response to this petition is in the final stages of review and the agency intends to issue the response shortly. If you have any questions regarding this matter, please refer to the docket number 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,

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

00P-1210

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