DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 10 2001

Richard 0. Wood
Bell, Boyd & Lloyd, LLC
Three First National Plaza
70 West Madison Street, Suite 3300
Chicago, Illinois 60602-4207

Re: Docket No. OOP-1210

Dear Mr. Wood:

We received your letter dated May 18, 2001 addressed to the Food and Drug Administration (FDA) reporting that at least three companies have included a cancer warning on their Over-the-Counter (OTC) coal tar products. You are requesting FDA to determine whether the presence of a specific warning on OTC coal tar medications renders the product misbranded under the Federal Food, Drug, and Cosmetic Act.

As you are aware, FDA recently responded to a citizen petition (Docket No. OOP-1210) requesting the agency to initiate a review of OTC coal tar products, restrict their sale to prescription status, and require that **a cancer** warning be added to the label of these products. In responding to this petition, FDA completed a thorough review of the relevant evidence, including all scientific information submitted with the petition, comments in the docket regarding these products, and a review of all relevant adverse event reports in our Adverse Event Reporting System. FDA concluded that "the data does not support that therapeutic use of coal tar in concentrations and formulations used in OTC drug products poses a risk of carcinogenicity." Furthermore, the agency concluded that there was not an adequate basis to restrict coal tar containing products to prescription use only or to require additional warning statements on these products.

The agency also carefully reviewed the studies submitted with the petition and concluded that there were such flaws in their design and conduct that they "add nothing to what is already known about carcinogenic liability of coal tar under conditions of OTC use. . ." FDA further determined that ". . at this time, there is no evidence that topical treatment of dermatological disorders with OTC coal tar shampoo, soap, or ointment drug products increases the risk of skin cancers." Thus, there is no scientific basis for adding additional carcinogenicity warnings to the labeling of these products.

OOP-1210

LET 3

We have recently become aware that there may be OTC coal tar products currently being marketed throughout the United States with additional warnings regarding the risk of cancer. The placement of any additional or modified warning on these products may render the products misbranded. We are evaluating the complex issues raised by warnings such as these and whether they are consistent with the appropriate provisions of our statute and regulations.

Thank you for your interest in this matter.

Sincerely yours,

Dennis E. Baker
Associate Commissioner
for Regulatory Affairs

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: 9.25.01

FROM: Director
Division of OTC Drug Products, HFD-S60

SUBJECT: Material for Docket No. 00P-1210/CP1 & C1 & C2

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. CP1 & C1 & C2

Charles J. Ganley, M.D.

Attachment