

FULBRIGHT & JAWORSKI L.L.P.

A REGISTERED LIMITED LIABILITY PARTNERSHIP

600 CONGRESS AVENUE, SUITE 2400

AUSTIN, TEXAS 78701

TELEPHONE: 512/474-5201
FACSIMILE: 512/536-4598

TERRY O. TOTTENHAM
PARTNER

INTERNET ADDRESS:
ttottenham@fulbright.com

DIRECT DIAL: 512/536-5444

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November 30, 2001

Commissioner of Food and Drugs
Food and Drug Administration
c/o Dockets Management Branch (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 01N-0196
Phenylpropanolamine; Proposal to Withdraw Approval of New Drug
Applications and Abbreviated New Drug Applications;
Opportunity for a Hearing
66 Fed. Reg. 42,665-71 (Aug. 14, 2001)
Supplemental Submission

Dear Commissioner:

On November 16, Arnold & Porter, on behalf of American Home Products Corporation ("AHPC") submitted a letter regarding a Notice of Opportunity for a Hearing ("NOOH") in the above referenced matter. This letter responded to objections submitted by the Public Citizen Health Research Group ("HRG") concerning the FDA's proposed withdrawal of its approval of certain new drug applications ("NDAs") and abbreviated new drug applications ("ANDAs") for products containing phenylpropanolamine ("PPA"). On November 21, 2001, Kaye Scholer, on behalf of Novartis Consumer Health, Inc. ("NCH") submitted a letter supporting AHPC's response. Finally, HRG replied to AHPC's November 16 letter on November 28, 2001.

Fulbright & Jaworski, on behalf of Bayer Corporation, agrees with the statements made in Arnold & Porter's November 16 letter and the statements made in Kaye Scholer's November 21 letter and fully supports AHPC's and NCH's assertions on this matter. Although all of Bayer Corporation's PPA-containing medications are immediate-release over-the-counter medications and are not subject to the original FDA notice, Bayer submits this letter as an interested party to the litigation.

AHPC's counsel asserted two main points (1) HRG and AHPC agree that the FDA "should remain neutral in state-law liability matters"; and (2) the FDA has "legal authority to advise the world of its neutrality." Regarding the first point, in its original submission, AHPC did not ask the FDA to issue a disclaimer that would protect the drug manufacturers from tort liability. AHPC simply requested that the FDA, consistent with its longstanding policy, issue a statement of

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neutrality regarding liability of the manufacturers and that the statements made in the NOOH should not be used as evidence in product liability cases. All parties recognize the potential influence any action or statement by the FDA could have on PPA-related litigation across the country. Therefore, it is essential that the FDA clarify the intended effect of any statement or action.

Second, HRG asserted that the FDA has no legal authority to issue a rule that has a substantive effect on products liability litigation. AHPC did not ask the FDA to publish a substantive rule. It simply requested that the FDA issue an advisory statement regarding the legal significance of the NOOH and reassert its neutrality in pending products liability cases. As both HRG and AHPC point out, the FDA has issued statements of this kind in the past, and continues to have the authority to do so.

Bayer Corporation also believes NCH did not falsely represent that "prior to the Yale HSP, there was no scientifically reliable evidence of an association between PPA and hemorrhagic stroke." Contrary to what HRG is attempting to advocate, NCH's statement is an accurate representation of what the HSP investigators stated in their final report published in the New England Journal of Medicine on December 21, 2000.

Finally, on November 28, HRG replied to AHPC's most recent submission. HRG asserted that AHPC was asking the FDA to make a disclaimer that would interfere with the role of state court judges in deciding evidence and that this was not a position of neutrality. Inevitably, the FDA's withdrawal of PPA-containing products will have a significant effect on state product liability cases. AHPC, NCH and Bayer are not asking the FDA to become involved in these cases or interfere with state court judges. They are simply requesting that the FDA issue a statement advising the general public that the FDA will remain neutral with regard to tort litigation involving private parties. The FDA has issued such statements in the past, and continues to have the power to do so.

In sum, HRG has misinterpreted what AHPC, NCH, and Bayer have asked the FDA to do. AHPC, NCH, and Bayer have simply requested that the FDA, as it has done in the past, reaffirm its neutrality in products liability cases. On behalf of Bayer, I respectfully submit these comments for your consideration.

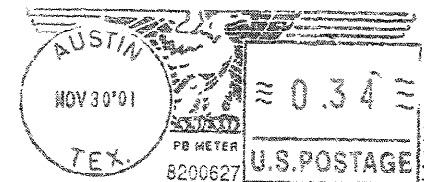
Very truly yours,



Terry O. Tottenham

TOT/aeg
30155856

TERRY O. TOTTENHAM
FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVENUE, SUITE 2400
AUSTIN, TEXAS 78701



COMMISSIONER OF FOOD AND DRUGS
FOOD AND DRUG ADMINISTRATION
C/O DOCKETS MANAGEMENT BRANCH (HFA-305)
5630 FISHERS LANE RM 1061
ROCKVILLE MD 20852

20857+0001

