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# ARNOLD & PORTER

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November 16, 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**

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Dear Commissioner:

On October 12, the Public Citizen Health Research Group (“HRG”) submitted objections to submissions on the referenced Notice of Opportunity for a Hearing (“NOOH”) from American Home Products Corporation (“AHPC”), Novartis Consumer Health, and Schering-Plough Health Care Products. Arnold & Porter submits this response on behalf of AHPC, to make two simple points:

1. HRG agrees with AHPC that FDA should remain neutral in state-law liability matters.
2. FDA has legal authority to advise the world of its neutrality.

**1. HRG and AHPC agree: FDA should remain neutral in state-law liability matters.**

HRG summarizes its review of FDA policy by quoting a statement from a 1979 *Federal Register* notice: “It is not the intent of the FDA to influence the civil tort liability of the [drug] manufacturer.” 44 Fed. Reg. 37,437. AHPC has simply requested that FDA adhere to this longstanding position. We do not want FDA to become involved in liability issues arising in private tort litigation.

Unfortunately, HRG misstates AHPC’s position. HRG claims that AHPC requested an official disclaimer (with a binding effect on state courts) that the withdrawal of PPA-containing drugs does not mean that the drugs were marketed negligently. **AHPC made no such request.** AHPC’s proposal was precise:

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The Commissioner [should] formally state that statements made in the NOOH, and any final order if the agency proceeds under 21 U.S.C. § 355 (e) (2), are not intended to – and should not – be used as evidence in product liability cases.

This proposed statement does not purport to bind any court or have a substantive legal effect. It merely advises courts about the significance that FDA believes should be attached in a civil tort litigation to statements made in the NOOH: to wit, none. Why?

- The NOOH is an advocacy statement of issues, urged by the Center for Drug Evaluation and Research (“CDER”).
- CDER’s statements in the NOOH were intended to meet legal criteria for withdrawal of approval of a new drug application (“NDA”) under section 505(e) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. 355(e). These criteria are different from the legal criteria applicable in private tort litigation.
- The NOOH statements were not intended to have a substantive effect on private tort litigation.
- The NOOH does not represent formal FDA findings made after completion of an adjudicated evidentiary hearing.
- Public policy should not compel a company that does not object to the withdrawal of its NDA to seek a formal evidentiary hearing simply to contest the unproven assertions in the NOOH. Such hearings would waste FDA resources for no useful purpose.

HRG has not disagreed with any of these points, which were made in AHPC’s initial filing.

## **2. FDA has legal authority to state its position.**

HRG asserts that FDA has no legal “authority to issue a rule with substantive effect on state product liability rules.” If that were AHPC’s request, we might agree with HRG.

But we only seek to have FDA state its view on the legal significance that it believes should be put on NOOH statements in civil product liability cases. As HRG points out, FDA has issued such statements for years, and HRG does not question the agency’s authority to make these statements.

HRG’s position is all the more difficult to understand when one considers that FDA made a substantively identical statement more than three years ago that HRG did

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not – and does not today – challenge. *See List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety or Effectiveness*, 64 Fed. Reg. 10,944, 10,945 (Mar. 8, 1999). Indeed, it appears from pages 4-5 of its filing that HRG believes FDA's statement in 1999 was appropriate and consistent with FDA's longstanding position against becoming involved in private tort litigation.

HRG also asserts that if FDA is going to issue a rule with substantive effect on state court liability rules, it must follow the notice-and-comment rulemaking procedures of the Administrative Procedure Act. Again, if that were AHPC's request, we might agree with HRG.

But the advisory statement we request is quite different. The statement requested by AHPC would not constitute an order or rule. It would determine no legal rights. It would not interpret or apply the Federal Food, Drug, and Cosmetic Act in a way to create an obligation. It is not "agency action" within the Administrative Procedure Act ("APA"), and its issuance would not require a notice-and-comment rulemaking proceeding. *See Pharmaceutical Manufacturers Ass'n v. Kennedy*, 417 F. Supp. 1224 (1979) (court held that FDA's "Orange Book" did not constitute "agency action" subject to the APA).

\* \* \*

In sum, AHPC has merely asked that FDA state that it is remaining neutral in tort litigation between private parties. FDA has the power to make such a statement and has done so in the past. And FDA **should** issue the requested advice. Product liability litigation about products containing PPA has already begun. In fact, over 200 suits (including 17 class actions) have been filed in federal and state courts against PPA manufacturers. Plaintiffs will attempt to use FDA's statements in the NOOH as evidence. In fact, Ramon Lopez, a noted plaintiff's lawyer, publicly described the NOOH as "his birthday present" from FDA.

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The NOOH was not written to help plaintiffs or to influence the outcome of these cases. FDA should say that.

Sincerely,

ARNOLD & PORTER

By:   
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Partner

cc: Sharon Heddish, Vice President  
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