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September 13, 2001 7953 '01 SEP 13 P3:52

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Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: FDA Docket No. 01N0196
Phenylpropanolamine; Proposal to Withdraw Approval of New Drug Applications ("NDAs") and Abbreviated New Drug Applications ("ANDAs).

Dear Sir or Madam:

We represent The Delaco Company ("Delaco"), successor in interest to Thompson Medical Company, Inc. ("Thompson Medical"). Prior to December 21, 1998, Thompson Medical had been a distributor of Dexatrim and other over-the-counter pharmaceutical products containing phenylpropanolamine ("PPA").

This letter responds to the Agency's August 14, 2001 Notice published at 66 Fed. Reg. 42665 (the "Notice") regarding the opportunity for hearing on the withdrawal of NDAs and ANDAs covering certain products containing PPA. Dexatrim was not the subject of an NDA and was marketed under the monograph process. According to FDA's Notice, the Agency intends to issue a separate Federal Register Notice to address such products. Delaco looks forward to the opportunity to review and consider its response to that Notice.

However, due to the potential effect the pending notice may have on any future Notice regarding products containing PPA, Delaco submits these comments for the Agency's consideration. Delaco believes the bases upon which the Agency relies in this Notice, including the report and conclusions from the Hemorrhagic Stroke Project (the "HSP") are flawed in many critical respects. These limitations include those issues raised by and on behalf of the Consumer Healthcare Products Association ("CHPA") at the October 19, 2000 hearing before the Nonprescription Drug Advisory Committee and the materials submitted by and on behalf of CHPA in connection with that hearing and process (including comments and materials submitted under cover of the May 24, 2000 and September 21, 2000 letters by CHPA). Those materials are incorporated by reference herein.

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In addition, Delaco respectfully submits that, should the Agency ultimately decide to withdraw approval for these or any other products containing PPA, any final rule or order withdrawing such approval should contain an acknowledgement from the Agency regarding the appropriate inferences to be drawn from a decision by FDA or a distributor to withdraw a previously-marketed drug from the market. In initially promulgating 21 C.F.R. § 216.24, listing drug products removed from the market for reasons of safety and effectiveness, the Agency emphasized that

> inclusion of a drug product on the list does not mean that the drug product was marketed negligently, was defective, or was marketed in breach of any warranty. Even after exhaustive clinical studies, safety problems may not become apparent until a drug product has been in commercial distribution for a significant amount of time, so the fact that a drug was removed or withdrawn from the market does not mean that the drug was improperly placed in commercial distribution.

64 Fed. Reg. 10944, 10945 (March 8, 1999). The same considerations should apply to any future withdrawal of PPA. Failure to so note could have the effect of discouraging future voluntary withdrawals where safety or efficacy problems do not arise until after FDA approval of the drug in question.

As noted previously, Delaco may also comment in response to FDA's forthcoming Notice regarding OTC and monograph products. Such comments might include further analysis with regard to the proposed bases for regulation of PPA in brands such as Dexatrim, especially in light of the unavailability to Delaco as yet of much of the underlying data and documentation generated by HSP.

We appreciate your consideration of these comments.

Sincerely,

Andrew S. Krulwich

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