DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 28 2003

Gene Koprowski
1415 North Dearborn Parkway
Chicago, IL 60610

Re: Docket No. 02P-0171/CP1

Dear Mr. Koprowski:

This letter responds to your citizen petition dated April 17, 2002. You request that the Food and Drug Administration (FDA) take the following actions:

1. Investigate the "misbranding" campaigns of third party groups, including the National Abortion Federation (NAF), Planned Parenthood, and other groups whose members benefit from the sale of RU-486 (mifepristone).
2. Amend section 301 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 331) to include misbranding or misleading promotion by third parties as prohibited acts.
3. Refer the matter to another federal agency with the authority to regulate deceptive commercial conduct.
4. Amend section 301 of the Act using language you propose.

On May 10, 2002, the NAF filed a comment to the docket. On August 3, 2002, you filed a response to NAF's comment.

We have considered the information submitted to the docket and address your requests in this response. For the reasons explained below, your petition is denied.

Your petition states that third parties are unethically exploiting a gap in the Act by conducting misleading branding campaigns. To support your statement, you cite the example of a NAF[1] campaign that you state was designed to promote the use of mifepristone.[2] You state that this campaign did not list the side effects of the drug product and was therefore deceptive and misleading as it implied the drug product was completely safe, without side effects.[3] You further

1. The NAF is a professional association of medical abortion providers in the United States and Canada.

2. Mifepristone was approved by FDA as safe and effective for the medical termination of intrauterine pregnancy through 49 days, on September 28, 2000.

3. You indicate that you have pursued legal action at the state level against NAF, by filing a lawsuit in the Circuit Court of Cook County, Illinois, alleging violations of the Illinois Deceptive Trade Practices Act. This case, *Nancy Koprowski, et al. v. the National Abortion Federation*, was dismissed on January 7, 2002.

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state that press reports indicate that abortion clinics are responsible for 75 percent of the sales of mifepristone, and thus the members of the NAF benefit from their misleading campaign through enhanced sales.

Section 502(n) of the Act indicates that FDA's statutory authority to regulate prescription drug advertising applies to advertising issued or caused to be issued by the manufacturer, packer, or distributor of a drug. Therefore, that misbranding provision of the Act does not apply to third party groups undertaking advertising campaigns independent of a manufacturer, packer, or distributor of a drug. FDA does not generally investigate what parties other than the NDA holder have to say about prescription drugs. When the NAF ads you cite first came to FDA's attention, the Agency followed its usual practice of checking with the NDA holder and determined that the NDA holder of mifepristone did not participate in the creation of, pay for, or place the NAF ads. Accordingly, absent additional facts, the Agency does not at this point have an adequate basis to warrant further investigation of these ads.

With regard to your second request, it appears that you may have confused the Act with the Agency's regulations. You request that we amend section 301 of the Act to include misbranding or misleading promotion by third parties as a prohibited act. However, in suggesting language for this amendment, you use the phrase "the amended regulation." Although the Agency is authorized to initiate rulemaking to amend its own regulations, the Agency does not have the authority to amend its governing statute, the Act. Only the U.S. Congress can pass a law amending a federal statute. You may choose to contact your elected representatives in Congress regarding your proposed amendment to the Act.

Finally, it is not clear that any other federal agency has jurisdiction over your requests. While the Federal Trade Commission's (FTC) jurisdiction extends to matters of consumer protection, including "unfair or deceptive acts or practices in or affecting commerce" (15 U.S.C. § 45(a)(1)), the FDA is not in a position to ascertain whether the third party campaign you cite would be subject to the FTC's jurisdiction. You may choose to communicate with the FTC, an attorney, or your elected representatives in the U.S. Congress regarding other federal jurisdiction over this matter.

Therefore, for the reasons discussed above, your petition is denied.

Sincerely yours,

John M. Taylor, III
Associate Commissioner
for Regulatory Affairs