Office of Secretary

#222

U.S. CONSUMER PRODUCT SAFETY COMMISSION

WASHINGTON, D.C. 20207

SEP 1 0 1975

MFR/PRVLBR NOTIFIED
____ No comments made
____ Comments attached
____ Excisions/Revisions
✓ Firm has not requested further notice
8/14/87

Mr. M. O. Maconachy
1572 Windsor Lane
Santa Ana, California 92705

Dear Mr. Maconachy:

This is in response to your letter of July 28, 1975, requesting information regarding federal jurisdiction over the product "Aqua Fem." The product apparently is designed and intended to introduce a solution under pressure into the vaginal tract. Based on the literature provided with your letter, this office is of the opinion that the product "Aqua Fem" is a "device" within the meaning of the Federal Food, Drug, and Cosmetic Act, and thus under the authority of the Food and Drug Administration and not the Consumer Product Safety Commission.

Section 201(h) of the Federal Food, Drug, and Cosmetic Act defines a device as meaning "instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to effect the structure or any function of the body of man or other animals." Although the literature describes the product as a "cosmetic appliance," it also makes "hygenic" claims, and it is known that vaginal douching has some effect on the natural biological status of the vaginal passage.

Therefore, since devices are excluded from the definition of the term "consumer product" under section 3(a)(1)(H) of the Consumer Product Safety Act, we have concluded that the Commission lacks jurisdiction over the product, "Aqua Fem." Should you wish to contact the Food and Drug Administration for further information, the address of the appropriate bureau is Bureau of Medical Devices and Diagnostic Products, U.S. Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852.

The opinion expressed herein is that of the Office of the General Counsel and is subject to change. Please contact us if you have further questions regarding this matter.

Sincerely,

Michael A. Brown
General Counsel

ADVISORY OPINION

Office of General Counsel
Consumer Products Safety Commission

July 28, 1975

I shall be anxiously waiting to hear from your office before making any final decisions concerning the manufature and sale of this appliance. I do not wish to become involved in the manufacture and sale of something that is not considered safe or in the best interests of the public.

Your prompt reply will be sincerely appreciated.

Thank you.

Sincerely,

M. O. Maconachy

MOM:bm

Enclosure: Brochure

Marion C. Maconachy
1572 Windsor Lane
Santa Ana, Ca. 92705

July 28, 1975

Office of General Counsel
Consumer Products Safety Commission
1750 K Street
Washington, D.C. 20207

Gentlemen:

Presently, I am in negotiation with a gentleman here in Southern California who recently acquired the rights and equipment for manufacturing the "Aqua Fem" appliance for douching. It would be in our interest to begin manufacturing this appliance, with parts already available, in the near future, should we reach an agreement on our proposed partnership.

This appliance is equipped with a small electic motor which provides the pressure and aeration of the douche solution. The handle is equipped with a control valve to regulate water flow and pressure.

I was in touch with Products Safety Office in Los Angeles. They recommended that I contact the Washington office. Accordingly, at your very earliest convenience, I would appreciate knowing the following:

1. Does this particular type of appliance come under your departmental control or another gov't. office?

2. If not your office, the name of the office under which it does come?

3. If under your office, has this particular model-- Aqua Fem-- previously been submitted for approval?

4. Is there published literature available containing the regulations for the manufacturing and sale of this type of appliance?

5. Assuming that there are government regulations and this particular model has not been approved, what steps would I have to take in order to obtain government approval?

Enclosed is some literature for the "Aqua Fem" appliance. If additional information is required by your office, please advise.