

May 10, 2004

TO: Division of Dockets Management (HFA-305)
Food and Drug Administration
5360 Fishers Lane, Room 1061
Rockville, MD 20851

FR: Cynthia Pearson, Executive Director
National Women's Health Network

RE: Comments on "Draft Guidance for Industry and FDA on Consumer-Directed
Broadcast Advertising of Restricted Devices" Docket Number 2004D-0042

On behalf of the National Women's Health Network, a consumer advocacy organization devoted to women and health, I am pleased to submit these comments on the Draft Guidance for Industry and FDA on Consumer-Directed Broadcast Advertising of Restricted Devices.

The Network is pleased that the draft guidance includes a variety of approaches ensure that consumers have access to device labeling information, including suggestions that are sensitive to privacy concerns, the fact that some consumers will be uncomfortable requesting information about devices, and the fact that some consumers have limited access to technology. However, we believe that the guidance can be strengthened in several areas.

1. The Network is concerned that the recommendation that sponsors disclose the most serious and the most common risks associated with a device is not sufficient. Sponsors should also be directed to provide information about the effectiveness of devices. If a device is not effective, any level of risk may not be acceptable. For implantable devices, information should be provided about effectiveness over the lifetime of the device.

In the case of silicone breast implants, we know that the most recent device that the FDA considered came with a very high reoperation rate up to three years after initial surgery, especially for reconstruction patients. We also know that all women with breast implants will have to remove or replace their implants at some point. FDA should be clear that the requirement that ads disclose the most serious and most common risks associated with a device should also apply to this kind of information.

2. Since the goal is to provide consumers with accurate and complete information, the Network recommends that in addition to directing consumers to a sponsor's website for additional information, device ads should direct consumers to the FDA website.