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26 APR 1979

ADVISORY COMMITTEE
#276

Mr. Leslie Fisher
Coordinator
Bureau of Maternal & Child Health
State of New York Department of
Health
The Governor Nelson A. Rockefeller
Empire State Plaza
Albany, N.Y. 12237

Dear Mr. Fisher:

This is in response to your April 11, 1979 letter to Sadye Dunn concerning the appropriate federal agency to refer complaints on home electrostatic air filters.

We have contacted the Office of Chief Counsel of the Food & Drug Administration (FDA) (copy of our letter to FDA enclosed), and they have informed us that whether an air cleaner is a "medical device" subject to their jurisdiction depends on whether medical claims are made for the product. Many electrostatic air cleaners apparently are "medical devices", although the particular cleaner purchased by Ms. Sills may not be.

For your information, home air cleaners which are not "medical devices" would be consumer products under the Commission's authority. In order to determine whether a particular air filter is a consumer product within CPSC jurisdiction or a medical device within FDA authority, we would need information on the labeling accompanying a product, its advertising and information on the manner in which the product is marketed.

I hope this is helpful to you.

Sincerely,

Stephen Lemberg
Assistant General Counsel

Enclosure
cc: OGC Chron
OGC Reading (2)
OGC File
CRoth:mtw:4/24/79

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
ROCKVILLE, MD. 20852

OFFICE OF THE
GENERAL COUNSEL

May 14, 1979

Stephen Lemberg, Esq.
Assistant General Counsel
U.S. Consumer Product Safety
Commission
Washington, D. C. 20207

Dear Mr. Lemberg:

I am writing in response to your letter of April 26, 1979. It is FDA's position that electrostatic air cleaners are not inherently medical devices because they have uses that are not for the diagnosis of disease or other conditions or for the cure, mitigation, treatment, or prevention of disease and are not intended to affect the structure or any function of the body. See 21 U.S.C. 321(h). In our view, electrostatic air cleaners, as a class, are consumer products.

A consumer product, such as an electrostatic air cleaner, can become a medical device, however, if medical or health-related claims are made for it. The making of such claims in connection with a device would bring it within the statutory definition of "device." Ordinarily, the relevant claims are those made by the manufacturer or distributor of the device in a product's label or labeling (see 21 U.S.C. 321(k) and (m)) or in advertising.

FDA has examined the labeling for the product purchased by Ms. Sills and has concluded that it does not make any medical or health-related claims. The product, therefore, is not a medical device and is not within the jurisdiction of FDA. The fact that Ms. Sills herself apparently is using the device for a medical or health-related purpose does not make it a device.

FDA does regulate the emission of ozone from products that are medical devices. See 21 C.F.R. 801.415. In order for such emissions to be within FDA's regulatory authority, however, the emitting product must itself be a medical device. The fact that ozone is emitted does not by itself make a product a medical device.

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The unsatisfactory result of this analysis is that some electrostatic air cleaners will be consumer products and others (indistinguishable in their physical properties) will be medical devices due to differences in labeling claims. This is the result produced by the statutes we administer. I see no proper way for FDA to expand its jurisdiction to include air cleaners that do not make medical or health-related claims because, in the absence of such claims, it cannot be said that such products "are intended for" any of the uses that make a product a medical device. Nor can I see any proper way for FDA to abdicate its authority over products that do make such claims.

I understand that Ms. Sills has withdrawn her petition. Nevertheless, I believe this letter will help in the future to remove misunderstandings concerning FDA's jurisdiction over products of this type.

Sincerely,

Richard M. Cooper

Richard M. Cooper
Chief Counsel
Food and Drug Division