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ADVISORY OPINION

#257

U.S. CONSUMER PRODUCT SAFETY COMMISSION

WASHINGTON, D.C. 20207

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OFFICE OF THE SECRETARY
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CONSUMER PRODUCT SAFETY COMMISSION

January 24, 1978

Mr. Bill Dollar
Contract Manager
Nelson-Brantley Glass Co. Inc.
P. O. Box 2785, Clover Station
Montgomery, Alabama 36105

Dear Mr. Dollar:

This is in response to your letter of September 19, 1977 requesting an exemption for lead x-ray protective glass from the Commission's safety standard for architectural glazing materials (16 CFR 1201). The Food and Drug Administration, in the enclosed correspondence dated January 4, 1978, has informed us that lead x-ray protective glass installed in doors or windows of radiation treatment rooms is an "accessory" to an x-ray machine and, is a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

Section 3(a)(1)(H) of the Consumer Product Safety Act (15 U.S.C. 2052(a)(1)(H)) excludes "devices" from the definition of "consumer product". Lead x-ray protective glass is not a "consumer product" as a result of this exclusion, and, therefore, would not be covered by the Commission's standard for architectural glazing materials. Consequently there is no need for an exemption from the standard for the lead x-ray protective glass you have described in your letter.

Sincerely,

Original signed by
Margaret A. Freeston

Margaret A. Freeston
Office of the General Counsel

Enclosure

AMERICAN REVOLUTION BICENTENNIAL 1776-1976

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

January 4, 1978

OFFICE OF THE
GENERAL COUNSEL

Theodore J. Garrish
General Counsel
U.S. Consumer Product Safety
Commission
Washington, D.C. 20207

Dear Mr. Garrish:

This is a reply to your inquiry of November 17, 1977, concerning whether lead x-ray glass used in doors or windows of radiation treatment rooms is a device subject to regulation by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act ("Act").

Section 201(h) of the Act provides, in relevant part, that the term "device" means:

> [A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--
>
> * * *
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals ....

An x-ray machine is unquestionably a device within the meaning of section 201(h). Since lead x-ray glass used in doors or windows of radiation treatment rooms permits the safe use of an x-ray machine, it is an "accessory" to an x-ray machine and, under section 201(h), also a device. All medical devices are, of course, subject to regulation by the Food and Drug Administration.

Sincerely,

Richard M. Cooper
Chief Counsel

RECEIVED
JAN 9 1978
Consumer Product
Safety Commission
Office of the
General Counsel

NEL/BRAN

NELSON-BRANTLEY GLASS CO., INC.

P. O. BOX 2785, CLOVERLAND STATION • MONTGOMERY, ALABAMA 36105
TELEPHONE 269-4337

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September 19,1977

Mr. S. John Byington, Chairman
U.S.Commission for CPSC (16CFR 1201)
Washington, D.C. 20207

Gentlemen:

We wish to request an exemption to the regulations requiring safety glazing material to be installed in doors-16CFR1201 (A0(7).

We are fabricators and installers of glass and glazing products and have contracted to install the glass and storefront material at Jackson Hospital, Montgomery, Alabama. There are doors at the radiological area which, for health and safety reasons must have X-ray protective glass, which cannot be tempered because of the high lead content.

Please issue a ruling or exemption on this as soon as possible.

Yours very truly,

Bill Dollar

Bill Dollar, Contract Manager

BD/mn

cc: NGDA
Washington,D.C. 20036

Give us a break/we'll give you the service that makes the difference