

IN THE MATTER OF
ZENITH LABORATORIES, INC., ET AL.

Docket 8426. Order, June 3, 1975

Show cause order of July 24, 1973, proposing modification of the order to cease and desist vacated.

Appearances

For the Commission: *J. Thomas Rosch.*

For the respondents: *David R. Simon, Simon & Allen, Newark, N.J.*

ORDER VACATING ORDER PROPOSING MODIFICATION OF ORDER TO
CEASE AND DESIST

On Apr. 13, 1973, respondent Zenith Laboratories, Inc. (Zenith), petitioned the Commission to reopen the consent order, dated Mar. 30, 1962, for the purpose of modifying said order by setting aside the order in its entirety. The 1962 consent order requires respondent to cease and desist from:

1. Disseminating or causing to be disseminated any advertisement by means of the United States mails or by any means in commerce, as "commerce" is defined in the Federal Trade Commission Act, which advertisement:

(a) Uses the terms "quality control" or "exacting controls," or any other words or terms of similar import or meaning; or

(b) Represents, directly or indirectly:

(1) That respondents have an adequate control system, or misrepresents the nature or extent of the procedures used by them in the manufacture, preparation or distribution of drugs or food.

The Commission concluded that good cause had been shown for modifying the above provisions of the order, but not as respondent requested, and so, by order of July 24, 1973, reopened this proceeding

and ordered respondent Zenith to show cause why the order should not be modified by requiring respondent Zenith to cease and desist from:

1. Disseminating or causing to be disseminated any advertisement by means of the United States mails or by any means in commerce, as "commerce" is defined in the Federal Trade Commission Act, which advertisement:

(a) Uses the terms "quality control" or "exacting controls," or any other words or terms of similar import or meaning; unless respondents also state in the same advertisement that such controls are required of all drug manufacturers pursuant to the standards set by the Federal Food, Drug, and Cosmetic Act, as amended; *Provided, however*, That such controls are in fact in conformance with the standards set by the Federal Food, Drug, and Cosmetic Act, as amended.

(b) Represents, directly or indirectly:

(1) That respondents have a more exacting quality control system than prescribed by the Federal Food, Drug, and Cosmetic Act, as amended, or misrepresents the nature or extent of the procedures used by them in the manufacture, preparation or distribution of drugs or food.

Paragraph 1(a)

Zenith, in its answer dated Aug. 24, 1973, requested that the Commission modify the consent order to permit it to use the terms "quality control" and "exacting controls" in its advertisements, without the proposed qualifying language (*i.e.*, "that such controls are required of all drug manufacturers pursuant to the standards set by the Federal Food, Drug and Cosmetic Act, as amended"). The grounds of Zenith's objections were that (1) the qualifying language could be read to imply that FDA approved of the company's quality controls, when a FDA regulation specifically prohibits a party from advertising that it has a new drug application approved by FDA; (2) it would be impractical for Zenith to include such wording; and (3) no other company is required to make the subject disclosure.

The Food and Drug Administration, by letter dated Nov. 16, 1973, similarly recommended against requiring the qualifying language, as "it appears * * * that this would be inequitable unless it were enforced against all manufacturers," and, in addition, might give rise to the "possible implications that the Food and Drug Administration has approved the company's quality control standards when, in fact, that is not the situation."

Counsel supporting the complaint concur in these recommendations that the 1962 order not be modified as proposed by Paragraph 1(a). We agree.

Paragraph 1(b)(1)

Order

85 F.T.C.

No objection to this modification was made by either FDA or respondents. We agree, however, with counsel supporting the complaint that the subject modification should be rejected. Representations as to "quality control" or "exacting controls" (representations which would be permissible under the modification) "should be permitted," counsel supporting the complaint point out, "[only] when respondent's controls significantly exceed the minimum requirements of the law * * *." It is our opinion that many consumers tend to believe that firms in their manufacturing processes comply with the standards set by law, and, as a consequence, the use of such terms as "quality control" may well create the impression that the standards employed by the manufacturer exceeds those set by law. It follows, then, that since the subject provision is intended to prohibit representations that quality controls exceed those prescribed by FDA, representations as to "quality controls" or "exacting controls" should be proscribed. Accordingly,

It is ordered, That the Commission's show cause order of July 24, 1973 proposing modification of the order to cease and desist issued in this matter on Mar. 30, 1962, be, and it hereby is, vacated.